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APPLICATION NUMBER: 60/525,778

FILING DATE: *November 26, 2003*

RELATED PCT APPLICATION NUMBER: PCT/US04/39620

Certified by

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname		Residence (City and either State or Foreign Country)	
Williams		Robert		607 Drew Drive, Saint James, NY 11780	
Hartman		Steve		42 Wheatfield Lane, Commack, NY 11725	
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
INJECTOR CONFIGURATION VIA REMOTE INJECTOR REMOTE CONTROL					
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<input checked="" type="checkbox"/> Customer Number		28990		 Number Pat Code Label here 28990	
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification		Number of Pages		<input type="checkbox"/> CD(s), Number	
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METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
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Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME

Thomas J. Parker

TELEPHONE

(212) 626-4187

Date

11/26/03

REGISTRATION NO.

42,062

(if appropriate)

Docket Number:

0008913-0051 A

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C.

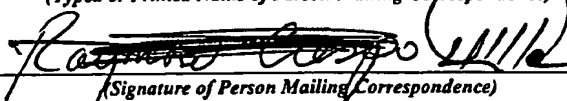
P19LARGE/REV05

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Serial No. TBA	Filing Date November 26, 2003	Examiner TBA	Group Art Unit TBA
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Invention: **INJECTOR CONFIGURATION VIA REMOTE INJECTOR REMOTE CONTROL**

I hereby certify that this Provisional Application For Patent Cover Sheet and Specification 55 pages
(Identify type of correspondence)
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Brief Summary of Invention:

This invention embodies the idea of utilizing injector electronics hardware and software design as part of the system, to dynamically, create, modify, store and delete operational data and user information on one part of an injector system (injector or remote) using another part of injector system. For instance, in the new release upcoming release of the EMPOWERCTA injector, foreign language displays on the injector head will be downloaded and stored in non-volatile memory or NON-VOLATILE DATA STORAGE MEDIUM from the remote control without having to power the system down. This will permit users to perform dynamic software feature updates to one component of the injector system, namely the injector head without the need to change hardware, update hardware, reprogram with an external programming device.

Novel Features and Advantages:

Some of the novel features and advantages of the Language Update are:

- By the press of a key on an electronic device connected to the system, the user can update the user-displayed messages to various other languages beside English.
- System can display a wide of variety of languages without any hardware modifications to the various components.
- A system previously configured in one language can easily be updated to another language.
- It is broadly contemplated that this medical injector design architecture could be extended to a multitude of user interface elements.

Problems Solved by this Invention:

The main problems solved by this invention are:

- All systems can be configured at one language at factory and set to any language once installed on-site.
- System can be easily updated to add additional languages in the future by updates of software.
- No hardware modifications are required to system to update language.
- Each device of the system can be dynamically updated to a different language via software control.

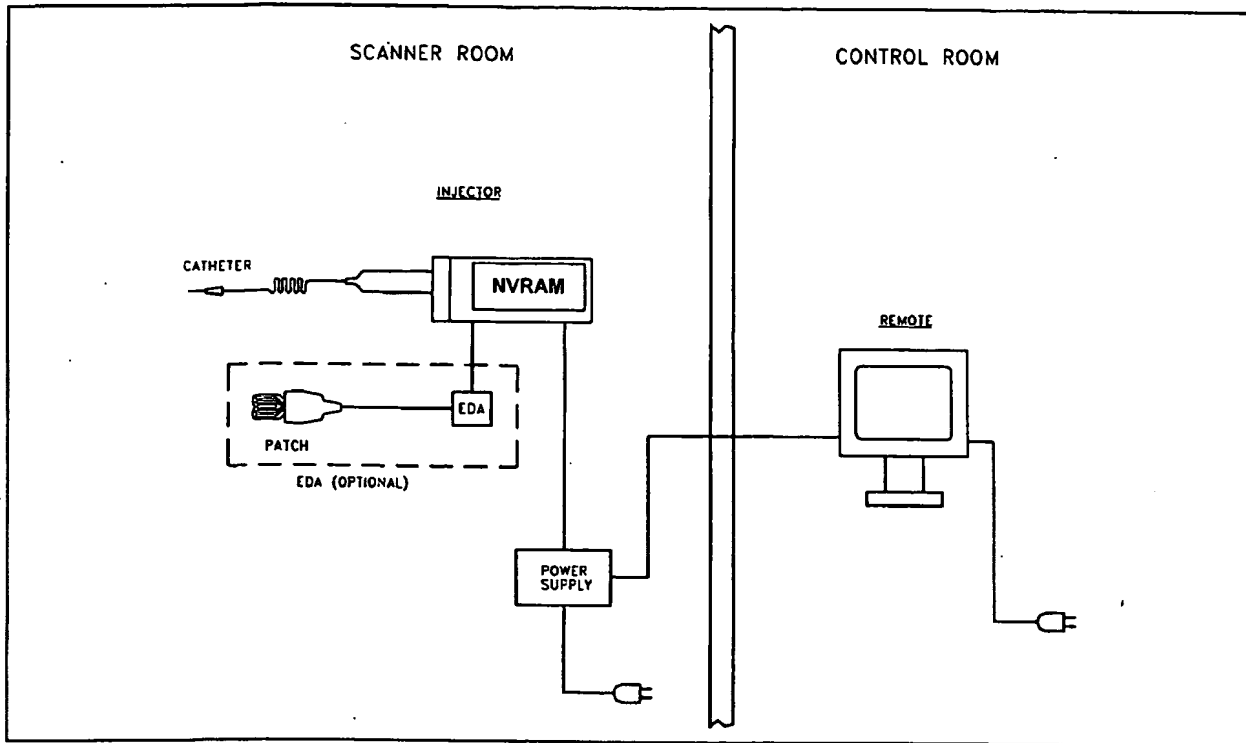
Prior Solutions and their Disadvantages:

Previously, the user would be required to:

- Pre-configure system at factory prior to customer receiving product.
- No electronic display of foreign languages text on the injector head.
- Exchanging "PROM" on each device to a new language
- Limit device to update of messages on Remote Control only and have no displayed messages on Injector or any ancillary device.
- Have key on device that updates the language on that device only.

Detail d Description of the Invention:

The figure below details the typical setup of a CT Injector System. This diagram is used to illustrate how the devices are interconnected. The CT Injector is located in the scanner room. It communicates with the Remote in the control room through a wired link. There is a communication cable routed between the Remote and the power supply. Thereafter a communication/power cable is connected from the power supply to the Injector. Connected to the Injector via cable interconnect is an ancillary device (Extravasation Detection Accessory).



Via the Remote Control, the user can press a Language Selection Key. When pressed, a pop-up window is displayed. The touchscreen window displays the current language and the available languages that the system can display.

Upon touching one of the available Languages, the selected Language is highlighted and the Language Selection window will disappear.

The Remote will access its database and transmit a message to the Injector to update the selected Language.

While the Remote and Injector are updating their languages, the Injector and Remote are unavailable for use. At the conclusion of a successful Language update, the Injector and Remote messages are displayed in the selected language. There is no need to power on or off the system.

The system will remember the latest selected language and upon future power-up will display the messages in the last selected language. The system will have the ability to detect a language mismatch between the Injector and Remote. The user will be prompted with a message to correct this mismatch.

This idea can be used to incorporate the following additional solutions:

- a) The Injector interface also could be used to update the language of the system.
- b) Deployment of Non-Volatile RAM (NVRAM), particularly Flash memory technology to preserve changes should they then be operated independently without a communications link
- c) The communication link between the Injector and Remote could be wireless for purposes of updating NVRAM data.
- d) Other ancillary injector components (For example EDA displayed messages) could be updated via this interface.

References to Other Patient Applications:

To this date, we are not aware of any references, patent applications, or other publications of which are pertinent to this invention.

Proprietary Materials from Outside Sources

To this date, we are not aware of any proprietary materials obtained from an outside vendor that was used to develop this invention.

What we claim

- 1) A medical injection system consisting of an fluid injector component, remote control component and other relevant operational electro-mechanical components in support of medical fluid injection whereby data communications between components exist between components;

wherein one or more of the components of the injection system possesses non-volatile memory whose data can be created, modified, deleted, changed through the user interface by one of the other components of the system for purposes of modifying the user interface, feature set or other visible feature of that part of the system whose NON VOLATILE DATA STORAGE MEDIUM is being modified.

- 2) The medical injector system of claim 1 where software produced user interface messages on the injector head can have their language created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to injector head via the remote control user interface through the data communication link between injector head and remote control.
- 3) The medical injector system of claim 1 where software produced graphics on the user interface belonging to the injector head can be created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to the injector via the remote control

user interface through the data communication link between injector head and remote control.

- 4) The medical injector system of claim 1 where software based parameters governing user interface appearance and available features can be created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to the injector via the remote control user interface through the data communication link between injector head and remote control.
- 5) The medical injector system of claim 1 where software based parameters governing user interface appearance and available features of the component possessing operable NON VOLATILE DATA STORAGE MEDIUM belonging via the user interface of any other component of the injector system through the data communication link between these components.
- 6) The medical injector system of claim 1 where software produced display of syringe pressure on the injector head display can be invoked or removed by data created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to injector head via the remote control user interface through the data communication link between injector head and remote control, or between the injector head and another component of the injector system.
- 7) The display of syringe pressure on the injector head during an injection.
- 8) The display of injector head syringe pressure on the injector head in claim 7 where pressure is displayed in a continuously updated real time format.
- 9) The display of injector head pressure on the injector in claim 7 where displayed pressure data includes its time history for the duration of the injection.
- 10) The medical injector system of claim 1 where protocol and procedural data as normally defined and limited to the remote control can be created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to the injector via the remote control user interface through the data communication link between injector head and remote control.
- 11) The injector system of claim 10 where protocol and procedural data can be accessed and by the user through the injector user interface without the remote control being either turned on or connected via data communication to the injector head.
- 12) The injector of claim 10 where the user can administer an injection protocol or procedure through data stored in NON VOLATILE DATA STORAGE MEDIUM in the injector head, within the confines of the injector user interface without the remote control being either turned on, active, or having a connection to the injector head via its data communication path.

The above claims in and of themselves provide the essences of the invention and are not intended to be complete, exhaustive and inclusive of E-Z-EM's utilization of this invention.

Abridged for Invention Disclosure



Visualize a healthier world.

EMPOWERCT Injector System System Specification Document No. 018-9001

Originated by: Bob Williams
Date: May 16, 2000

Approvals:

Arthur Zimmet 06/23/00
A. Zimmet (Special Projects Management)

Joe Palma 07/13/00
J. Palma (Marketing Management)

Tom McLaughlin 07/06/00
T. McLaughlin (Marketing)

Peter Aprile 06/23/00
P. Aprile (Regulatory Affairs)

Jeff Cushner 06/23/00
J. Cushner (Marketing)

Michael Davis, M.D. 06/23/00
M. Davis, M.D. (Medical Affairs)

Bob Williams 06/23/00
B. Williams (Engineering)

Victor Ugbogbo 06/23/00
V. Ugbogbo (Quality)

George Rehl 06/23/00
G. Rehl (Operation)

Steven Hartman 06/23/00
S. Hartman (Engineering)

Dan Werlick 06/23/00
D. Werlick (Engineering)

Alan Cross-Hansen 06/23/00
A. Cross-Hansen (Engineering)

Tito Tengco 06/23/00
T. Tengco (Engineering)

REV	DCN#	DESCRIPTION OF CHANGE	DATE	APVD
-	N/A	Initial Release	See above	See above
A	6201	See DCN	02/28/01	SH/RW
B	6215	See DCN	09/05/01	SH/RW
C	6231	See DCN	11/8/01	SH/RW
D	6300	Removed defibrillator proof rating, See pages 4 & 15 for changes	02/06/02	SH/ACH
E	6307	Added "Arming" at the Injector feature	2/28/02	SH/ACH
F	6326	Added new Catalog numbers and software compatibility requirement	5/14/02	SH/ACH
G	6339	Changed Arming timing at Injector to two seconds	6/11/02	SH/GR
H	6349	Added Philips Interconnect Specification	8/2/02	SH/ACH
J	6395	Update Language Selection and add password to Philips Interconnect Selection	2/11/03	SH/ACH
K	6409	Added additional features to system	4/10/03	SH/ACH
L	6450	Added pressure limit unit feature to Remote.	10/10/03	SH/ACH
M	6456	See DCN		

PAGE REVISION TABLE

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4.5.4 Setup Menu Screen

The Setup Menu Screen is used to tailor the system to the user. The Setup Menu Screen can only be accessed through the Main Menu by pressing the SETUP key. The Help Menu System is also available.

4.5.4.1 Inactive Message Display Area

The following Inactive Message Display Area is used to display information that cannot be modified by the user.

System Status Message

The message **"Warning!!! Invalid Service Password. Please try again."** to any incorrect password entered for Service. This message will disappear once the OK key is pressed on the pop-up message area.

When an invalid setting is entered via a pop-up keypad in SETUP, a pop-up message area will display **"Warning!!! Invalid Parameter, Please check allowable range."** This message will disappear once the OK key is pressed on the pop-up message area.

The message **"UNSUCCESSFUL LANGUAGE TRANSMISSION, PLEASE TRY AGAIN"**, if an unsuccessful transmission of the newly selected Language has occurred.

4.5.4.2 Active Input Display Areas

The following Active Input Display Areas are used to display information and can be used to change specific information via pop-up keyboard or keypad.

Date

If this key is pressed, the current setting and format for the date will be displayed. This key will allow the user to change the date, and additionally select the date display format. The default setting is in "MM/DD/YY" format. Once touched, a pop-up numeric keypad will be displayed on the screen that contains the numeric "0-9", "Clear", "Cancel" "Bksp", "Enter", and "Date Display Format" keys.

If the "Date Display Format" key is touched, it will change the display format to "DD/MM/YY". This is a toggle action key changing the date display format between two possible formats. Using the pop-up keypad, the user can enter the new date. Data entered will be checked to determine if the entry is valid after the "Enter" key is pressed. Incorrect entries will prompt the user as described in section 4.5.4.1.

Language Selection

If this key is pressed, a pop-up keypad is displayed. The user is required to enter an alpha/numeric password. Upon successful entry of the password, a pop-up window is opened with the current language being displayed. In addition, the current available languages will be displayed. The default setting is "ENGLISH".

Upon touching one of the available Languages, the selected Language is highlighted and the user has to touch the "Enter" key to complete the selection of the new Language. Once the "Enter" key is touched, the pop-up Language Selection window will disappear.

If the user has selected a new Language, the Remote will go into the Language Update mode. In this mode, the Remote will access its stored Language database. In addition, it will transmit a message to the Injector to update the selected Language. The language selection on the Remote can be performed if there are no communications between the Injector and Remote. The Injector can only be updated if there is successful communications between the Injector and Remote.

While the Remote and Injector are updating their languages, the Injector and Remote are unavailable for use. At the conclusion of a successful Language update, the Injector and Remote messages are displayed in the selected language.

The system will remember the latest selected language and, upon future power-up, will display the messages in the last selected language.

Under the condition that a language mismatch exists between the Injector and Remote, the Remote will alert the user with the message, "Language Mismatch, Select Desired Language". This message will be displayed in both the language selected on the Injector and in the language selected on the Remote. This system cannot be armed until this mismatch is corrected.

PURPOSE:

The purpose of this document is to verify that the EmpowerCT Injector functions as described in section 4.4.2 of the System Specification document No. 018- 9001.

SCOPE:

The procedure described herein applies to the EmpowerCT Injector. This Software Test Plan contains a reasonable set of specific tests designed to validate all of the possible operating configurations of the EmpowerCT Injector while in the STOP mode as described in the System Specification document No. 018- 9001.

DEFINITIONS:

- Single Action Switch – A switch that causes a single action to occur regardless of how long it is depressed/latched.
- N/A – Non-Active; A membrane key is not active when it does not initiate any response from the injector when depressed.
- LOAD Position – The injector is pointed in a direction that is equal to or falls +/-15 degrees from vertical.
- RUN Position – The injector is pointed in a direction that is equal to or lower than 15 degrees below horizontal.

A nominal 100-millisecond tone will sound at the Injector when an active key is pressed unless otherwise specified.

Required Equipment:

Equipment	Quantity
EmpowerCT Injector	1
EmpowerCT Remote	1
EmpowerCT Power Supply Assembly	1
EmpowerCT Communication Cable	1
EDA Test fixture #017-8004	1
CT Fast*Load syringe cat. #6720	1
EmpowerCT Power/Communications Cable	1
EmpowerCT Injector Floor Stand Assembly	1

Test Setup

To perform any of the STOP mode software tests in this test plan, the Injector must be in a known state. This known state will be achieved by completing the following initial setup.

Initial Setup:

1. Connect the cable exiting from the bottom of the injector to the Communications/Power cable.
2. Connect the other end of the Communication/Power Cable to the Power Supply right hand port.
3. Connect one end of the Communications cable to the power supply left hand port and the other end to the back of the Remote.
4. Attach the Pendant switch to the Injector.
5. Connect the EDA Test Fixture # 017-8004 to the EDA module. Put both switches on the test fixture up & set the resistance to 100 ohms.
6. Power-up the Remote and the Injector.

Note:

For software releases 02.04a and higher, the EmpowerCT has incorporated into the system various foreign languages. A table at the end of this document will be utilized for the tester to verify that the various foreign languages messages are correct. During the test steps, the English message followed by the appropriate message number referring to the foreign language table is written for a verification step. Refer to the message number specified and utilize the appropriate column depending on the language being tested.

Following the following steps to test the activate the required foreign language:

1. Verify that the Messages "Injector or Remote Not Found" are not displayed on the Injector or Remote. If message is displayed, check all connections and as required re-power the entire system.
2. Press the SETUP key on the Remote Control.
3. Press the Language Selection key on the Remote Control.
4. Enter the E-Z-EM password to activate the foreign language selection table.
5. Select the appropriate foreign language.
6. Allow the system a few minutes for the software to be updated.
7. Verify that the system is now at the STOP Main Menu in a foreign language.

Software revision being tested: _____

Language Tested: _____

Tests performed by: _____ Date: _____

VERIFICATION OF THE POWER UP SCREEN

This section is to verify the information that is displayed for approximately 5 seconds during the power up sequence.

Turn the Injector off and then on.

Verify that the following information is displayed on the Graphics display of the Injector immediately after being powered on:

Information on the Injector Graphics Display	Initials
The E-Z-EM logo	
The Software Release Identifier	
The Name of the Product	

Verify the following on the Injector during Power-up:

Functions/Information	Initials
No Membrane keys are active	
The display information is displayed for at least five seconds	
After five seconds, the screen is changed to the stop mode screen.	

Section 4.4.2.1 OF SYSTEM SPECIFICATION

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: Replace Syringe

Setup:

1. Rotate the Injector to the LOAD position
2. Cycle power to the Injector off and then on.
3. If necessary, place the Injector in the Replace Syringe position by pressing the REPLACE SYRINGE or msg. no. 1 membrane button.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 2	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 4	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

4. ☐ Verify that Membrane Key 1 must be held at least for one second to initiate the AUTO-INITIALIZE function (see Section 4.4.2.2).
5. ☐ Verify while Membrane Key 1 is held at least for one second that there is one short followed by one long acknowledgement tone and then the AUTO-INITIALIZE function is initiated.
6. ☐ Verify that if Membrane Key 1 is held for less than one second the AUTO-INITIALIZE function is not initiated.
7. Press any membrane key to stop the AUTO- INITIALIZE function. If necessary, retract to the Replace syringe position.
8. ☐ Verify that Membrane Key 2 is not active
9. ☐ Verify that Membrane Key 3 places the Injector into MANUAL mode. (See Section 4.4.2.4)
10. Cycle power to the Injector off and then on.
11. ☐ Verify that Membrane Key 4 is not active
12. ☐ Verify that Membrane Key 5 is not active
13. Tilt the Injector out of the LOAD position but not the RUN position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

14. Tilt the Injector to the RUN position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

15. Tilt the Injector to the LOAD position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 2	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 4	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

16. Use the Injector Hand Knob to advance the Injector ram out of the Replace Syringe position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL OR REPLACE SYRINGE or msg. no. 6	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 4	
Membrane Key 4	N/A	
Membrane Key 5	Replace syringe or msg. no. 01	

17. Use the Injector Hand Knob to retract the Injector ram back to the Replace Syringe position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 2	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 4	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

Section 4.4.2.2 OF SYSTEM SPECIFICATION

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: In Process
Auto- Initialize Invoked

Setup:

1. If not already in this position, place the Injector in the Replace Syringe position by pressing the Replace Syringe membrane button.
2. Press and hold for at least two seconds Membrane Key 1.
3. ☐ Verify that the Auto-Initialize function has been invoked.

Confirm that the following information is displayed:

Graphics Display Area	Displayed information	Initials
Syringe Volume Indicator	--- ML	
Message Area	AUTO-INITIALIZATION IN PROGRESS, PRESS ANY KEY TO STOP or msg. no. 07	
Membrane Keys 1-5	"STOP" or msg. no. 08	

4. ☐ Verify that Membrane Key 1 stops the process and the Syringe Volume displays --- ML.
5. Restart the AUTO-INITIALIZE process by pressing the "AUTO-INITIALIZE" Membrane Key.
6. ☐ Verify that Membrane Key 2 stops the process and the Syringe Volume displays --- ML.
7. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.
8. ☐ Verify that Membrane Key 3 stops the process and the Syringe Volume displays --- ML.
9. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.
10. ☐ Verify that Membrane Key 4 stops the process and the Syringe Volume displays --- ML.
11. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.
12. ☐ Verify that Membrane Key 5 stops the process and the Syringe Volume displays --- ML.
13. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.
14. Tilt the Injector out of the LOAD position but not in the RUN position.

15. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

16. ☐ Verify that tilting the Injector out of the LOAD position stops the auto-initialization process.

17. Tilt the Injector to the LOAD position.

18. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.

19. Tilt the Injector to the RUN position.

20. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

21. ☐ Verify that tilting the Injector to the RUN position stops the auto-initialization process.

22. Tilt the Injector to the LOAD position.

23. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.

24. ☐ Verify that once the system stops when the Injector ram reaches the 0 ml position and the Syringe Volume displays 0 ML.

25. Retract the Injector Ram to the Replace Syringe position. Press the Manual Key. Start the Auto-Initialize process.

Confirm that the initial that the following information is displayed:

Graphics Display Area	Displayed information	Initials
Syringe Volume Indicator	--- ML	
Message Area	AUTO-INITIALIZATION IN PROGRESS, PRESS ANY KEY TO STOP Or msg. no. 07	
Membrane Keys 1-5	"STOP" or msg. no. 08	

Confirm that after five seconds that the following information is displayed:

Graphics Display Area	Displayed information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	AUTO-INITIALIZATION IN PROGRESS, PRESS ANY KEY TO STOP Or msg. no. 07	
Membrane Keys 1-5	"STOP" or msg. no. 08	

26. Tilt the Injector out of the LOAD position.

27. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	N/A	

28. Retract the Injector Ram to the Replace Syringe position. Press the Manual or msg. no. 04 Key and start the auto-initialization process. After the process, immediately starts press any key to stop the process.

29. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲ ▲	
Membrane Key 5	Replace syringe or msg. no. 01	

30. Press Membrane Key 1 and start the auto-initialization process. Allow the process to complete.

31. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	REPLACE SYRINGE OR MSG. NO. 01	

32. Retract the Injector ram to the Replace syringe position. Press the Manual Key. Start the Auto-Initialization process.

33. When the Injector volume displays XXX ml, press any key to stop the auto-initialization process.

34. Confirm the following is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

35. Retract the Injector Ram to the Replace syringe position. Press the Manual Key. Start the Auto-Initialization process. Immediately as the process begins, tilt the Injector out of the LOAD position.

36. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

37. Tilt the Injector back to the LOAD position.

SECTION 4.4.2.3 of system specification

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Between 0 ml and Replace Syringe Position

System Not Initialized

Setup:

1. If not already in this position, place the Injector in the Replace Syringe position by pressing the REPLACE SYRINGE or msg. no. 01 membrane button.
2. Depress Membrane Key 1 labeled AUTO-INITIALIZE or msg. no. 03
3. Cancel the AUTO-INITIALIZE procedure before 0 ml is reached by pressing any membrane key.
4. ☐ Verify the Injector ram is between 0 ml and the Replace Syringe position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL OR REPLACE SYRINGE Or msg. no. 06	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 04	
Membrane Key 4	N/A	
Membrane Key 5	Replace syringe or msg. no. 01	

5. ☐ Verify that Membrane Key 1 must be held at least for one second to initiate the AUTO-INITIALIZE function (see Section 4.4.2.2).
6. ☐ Verify while Membrane Key 1 is held at least for one second that there is one short followed by one long acknowledgement tone and then the AUTO-INITIALIZE function is initiated.
7. ☐ Verify that if Membrane Key 1 is held for less than one second the AUTO-INITIALIZE function is not initiated.
8. Press any membrane key to stop the AUTO- INITIALIZE function before it reaches the 0 ml position.
9. ☐ Verify that Membrane Key 2 is not active.
10. ☐ Verify that Membrane Key 3 places the Injector into MANUAL mode. (See section 4.4.2.4)
11. Cycle power to the Injector off and then on.
12. ☐ Verify that Membrane Key 4 is not active.

13. ☐ Verify that Membrane Key 5 must be held at least for one second to initiate the REPLACE SYRINGE function (see Section 4.4.2.10).
14. ☐ Verify while Membrane Key 5 is held at least for one second that there is one short followed by one long acknowledgement tone and then the REPLACE SYRINGE function is initiated.
15. ☐ Verify that if Membrane Key 5 is held for less than one second the REPLACE SYRINGE function is not initiated.
16. Press any membrane key to stop the REPLACE SYRINGE function before it reaches the REPLACE SYRINGE position.
17. ☐ Verify that Syringe Volume displays --- ML.
18. Tilt the Injector out of the LOAD position.

19. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

20. Tilt the Injector back to the LOAD position.
21. Tilt the Injector to the RUN position.

22. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

23. Power the Injector off and then on. Tilt the Injector back to the LOAD position.

24. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL OR REPLACE SYRINGE Or msg. no. 06	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 04	
Membrane Key 4	N/A	
Membrane Key 5	Replace syringe or msg. no. 01	

25. Press the Manual Key. Make sure that the syringe is below 200 ml.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲	
Membrane Key 5	Replace syringe or msg. no. 01	

27. Tilt the Injector out of the LOAD position.

28. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

29. Tilt the Injector back to the LOAD position.

30. Tilt the Injector to the RUN position.

31. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

32. Tilt the Injector back to the LOAD position.

33. Use the hand knob to advance the Injector Ram forward till the syringe volume no longer displays --- ml and volume equals 200 ml.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify
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		Initials
Syringe Volume Indicator	200 ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	N/A	
Membrane Key 4	N/A	
Membrane Key 5	Replace Syringe or msg. no. 01	

34. Retract the Injector to the Replace Syringe position. Press the Manual Key. Press and hold the Slow Forward key for five seconds.

35. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲ ▲	
Membrane Key 5	Replace syringe or msg. no. 01	

36. Tilt the Injector out of the LOAD position.

37. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

38. Tilt the Injector to the LOAD position.

Section 4.4.2.4 of system specification

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Replace Syringe Position

Manual Key Selected

Setup:

1. If not already in this position, place the Injector in the Replace Syringe position by pressing the Replace Syringe membrane button.

2. Press the MANUAL or msg. no. 04 membrane key.

3. ☐ Verify that the Manual Key or msg. no. 04 is a single action key.

4. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	A	
Membrane Key 4	N/A	
Membrane Key 5	A A	

5. ☐ Verify that Membrane Key 1 must be held at least for one second to initiate the AUTO-INITIALIZE function (see Section 4.4.2.2).

6. ☐ Verify while Membrane Key 1 is held at least for one second that there is one short followed by one long acknowledgement tone and then the AUTO-INITIALIZE function is initiated.

7. ☐ Verify that if Membrane Key 1 is held for less than one second the AUTO-INITIALIZE function is not initiated.

8. Press any membrane key to stop the AUTO- INITIALIZE function. Retract back to the Replace syringe and press Manual.

9. ☐ Verify that Membrane Key 2 is not active.

10. Press and hold Membrane Key 3.

11. ☐ Verify that Membrane Key 3 moves the Injector Ram forward at approximately 1 ml/sec.

12. Release Membrane Key 3.

13. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving and that the syringe volume displays --- ml.

14. Retract back to the Replace syringe and press Manual.

15. ☐ Verify that Membrane Key 4 is not active.

16. Use the Replace syringe key to return to the Replace Syringe position. Press the Manual key or msg. no. 04 once at the REPLACE SYRINGE position.

17. Press and hold Membrane Key 5 for five seconds.

18. ☐ Verify that Membrane Key 5 moves the Injector Ram forward at approximately 10 ml/sec.

19. Release Membrane Key 5.

20. ☐ Verify that when Membrane Key 5 is released the Injector Ram stops moving.

21. ☐ Verify that the syringe volume displays "XXX" ml where "XXX" is the approximate location of the injector ram.

22. Bring the Injector Ram to the 0 ml position.

23. ☐ Verify that the syringe volume displays 0 ml.

24. Tilt the Injector out of the LOAD position.

25. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

26. Tilt the Injector back to the LOAD position.

27. Tilt the Injector to the RUN position.

28. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

29. Tilt the Injector back to the LOAD position.

30. Bring the Injector Ram back to the Replace Syringe position. Press Membrane Key 3 once. Press Membrane Key 3 for five seconds.

31. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲ ▲	
Membrane Key 5	REPLACE SYRINGE OR MSG. NO. 01	

32. Press and hold Membrane Key 1 until the Injector Ram reaches the 0 ml position.

33. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	REPLACE SYRINGE OR MSG. NO. 01	

34. Press the Replace Syringe key. Allow the Injector Ram to retract to the Replace Syringe position. Press the Manual Key.

35. Press Membrane Key 5 until the Injector displays XXX ml.

36. Confirm the following is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

SECTION 4.4.2.5 of system specification (SEE SECTION 4.4.2.9)

Section 4.4.2.6 OF SYSTEM SPECIFICATION

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: 0 ML

Setup:

1. If necessary, move the Injector Ram to the 0 ML position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	REPLACE SYRINGE or msg. no. 01	

3. ☐ Verify that Membrane Key 1 activates the AUTO- FILL screen and is a single action key (see section 4.4.2.7).
4. Press CANCEL or msg. no. 15 to return to the previous screen
5. ☐ Verify that Membrane Key 2 is not active.
6. Press and hold Membrane Key 3.
7. ☐ Verify that Membrane Key 3 moves the Injector Ram reverse at approximately 0.5 ml/sec.
8. Release Membrane Key 3.
9. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving.
10. Return the Injector Ram to the 0 ML position.
11. Press and hold Membrane Key 4.
12. ☐ Verify that Membrane Key 4 moves the Injector Ram reverse at approximately 10 ml/sec.
13. Release Membrane Key 4.
14. ☐ Verify that when Membrane Key 4 is released the Injector Ram stops moving.
15. Return the Injector Ram to the 0 ML position.

16. ☐ Verify that Membrane Key 5 must be held at least for one second to initiate the REPLACE SYRINGE function (see Section 4.4.2.10).

17. ☐ Verify while Membrane Key 5 is held at least for one second that there is one short followed by one long acknowledgement tone and then the REPLACE SYRINGE function is initiated.

18. ☐ Verify that if Membrane Key 5 is held for less than one second the REPLACE SYRINGE function is not initiated.

19. Return the Injector Ram to the 0 ML position.

20. Tilt the Injector out of the LOAD position.

21. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

22. Tilt the Injector back to the LOAD position.

23. Tilt the Injector to the RUN position.

24. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

25. Tilt the Injector back to the LOAD position. Cycle power on the Injector off and then on.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	✓	
Membrane Key 4	✓	
Membrane Key 5	REPLACE SYRINGE or msg. no. 01	

SECTION 4.4.2.7 of system specification

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: 0 ML
AUTO-FILL selected

Setup:

1. If necessary, move the Injector Ram to the 0 ML position.
2. Press the AUTO- FILL Key once.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	FILL VOL.=XXX ML PRESS + 5 OR + 25 TO INCREMENT. PRESS BEGIN AUTO-FILL TO START or msg. no. 13	
Membrane Key 1	+25	
Membrane Key 2	+5	
Membrane Key 3	-5	
Membrane Key 4	BEGIN FILL or msg. no. 14	
Membrane Key 5	CANCEL or msg. no. 15	

3. Press Membrane Key 1.
4. ☐ Verify that Membrane Key 1 changes the AUTO- FILL volume as displayed to 50 ml and acts as a single action key.
5. Press Membrane Key 1 a total seven more times.
6. ☐ Verify that Membrane Key 1 changes the AUTO- FILL volume increments 25 ml per key press and it acts as a single action key and after the seventh key press the auto-fill volume is equal to 25 ml.
7. Press Membrane Key 2.
8. ☐ Verify that Membrane Key 2 increments the auto-fill volume by 5 ml for every key press.
9. Press Membrane Key 3.
10. ☐ Verify that Membrane Key 3 decrements the auto-fill volume by 5 ml for every key press.
11. Press Membrane Key 5.
12. ☐ Verify that Membrane Key 5 returns to the 0 ML position screen.
13. Press the Auto-Fill or msg. no. 11 key.
14. Tilt the Injector out of the LOAD position.

15. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

16. Tilt the Injector back to the LOAD position.

17. Tilt the Injector to the RUN position.

18. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

19. Tilt the Injector back to the LOAD position.

20. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	✓	
Membrane Key 4	✓ ✓	
Membrane Key 5	REPLACE SYRINGE or msg. no. 01	

21. Press Membrane Key 1. Press Membrane Key 4.

22. ☐ Verify that Membrane Key 4 begins the AUTO- FILL function and fills the syringe to the selected fill volume (see section 4.4.2.8).

Section 4.4.2.8 of system specification

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: 0 ML
AUTO-FILL invoked

Setup:

1. Move the Injector Ram to the 0 ML position.
2. Press the AUTO- FILL Membrane Key once to invoke the AUTO- FILL screen.
3. Invoke the AUTO- FILL process by pressing the BEGIN FILL Membrane Key.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	AUTO-FILL IN PROGRESS, PRESS ANY KEY TO STOP or msg. no. 16	
Membrane Keys 1-5	STOP or msg. no. 08	

5. ☐ Verify that Membrane Key 1 stops the Injector Ram.
6. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
7. ☐ Verify that Membrane Key 2 stops the Injector Ram.
8. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
9. ☐ Verify that Membrane Key 3 stops the Injector Ram.
10. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
11. ☐ Verify that Membrane Key 4 stops the Injector Ram.
12. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
13. ☐ Verify that Membrane Key 5 stops the Injector Ram.
14. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
15. Tilt the Injector out of the LOAD position but not the RUN position.
16. ☐ Verify that tilting the Injector out of the LOAD position stops the Injector Ram.

17. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	N/A	

18. Tilt the Injector back to the LOAD position.

19. Repeat steps 1 – 3 to invoke the AUTO- FILL process.

20. Tilt the Injector to the RUN position.

21. ☐ Verify that tilting the Injector out of the LOAD position stops the Injector Ram.

22. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

23. Tilt the Injector back to the LOAD position.

24. Repeat steps 1 – 3 to invoke the AUTO- FILL process. Set the Auto-Fill Volume = 95 ml.

25. ☐ Verify that the Injector volume displays approximately 95 ml.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲	
Membrane Key 3	▼	
Membrane Key 4	▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

Section 4.4.2.9 of System Specification

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Between 1 and 200 ml

System Initialized and Loaded

Setup:

1. Using the arrow membrane keys, move the Injector Ram to a location somewhere between the 1 ml and 200 ml positions.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

3. Press and hold Membrane Key 1.

4. ☐ Verify that Membrane Key 1 moves the Injector Ram forward at approximately 1 ml/sec.

5. Release Membrane Key 1.

6. ☐ Verify that when Membrane Key 1 is released the Injector Ram stops moving.

7. Press and hold Membrane Key 2.

8. ☐ Verify that Membrane Key 2 moves the Injector Ram forward at approximately 10 ml/sec.

9. Release Membrane Key 2.

10. ☐ Verify that when Membrane Key 2 is released the Injector Ram stops moving.

11. Press and hold Membrane Key 3.

12. ☐ Verify that Membrane Key 3 moves the Injector Ram reverse at approximately 0.5 ml/sec.

13. Release Membrane Key 3.

14. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving.

15. Press and hold Membrane Key 4.

16. ☐ Verify that Membrane Key 4 moves the Injector Ram reverse at approximately 10 ml/sec.

17. Release Membrane Key 4.

18. ☐ Verify that when Membrane Key 4 is released the Injector Ram stops moving.

19. Press and hold Membrane Key 5 for at least one second. Release after at least one second.

20. ☐ Verify that Membrane Key 5 must be held at least for one second to initiate the REPLACE SYRINGE function (see Section 4.4.2.10).

21. ☐ Verify while Membrane Key 5 is held at least for one second that there is one short followed by one long acknowledgement tone and then the REPLACE SYRINGE function is initiated.

22. ☐ Verify that if Membrane Key 5 is held for less than one second the REPLACE SYRINGE function is not initiated.

23. Press any membrane key to stop the REPLACE SYRINGE function before it reaches the REPLACE SYRINGE position.

24. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

25. Tilt the Injector out of the LOAD position but not in the RUN position.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	N/A	

27. Tilt the Injector back to the LOAD position

28. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲	
Membrane Key 3	▼	
Membrane Key 4	▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

29. Use Membrane Key 2 to advance the Injector ram till it reaches 0 ml.

30. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	▼	
Membrane Key 5	REPLACE SYRINGE or msg. no. 01	

31. Use Membrane Key 3 to retract the Injector Ram till it reaches 10 ml.

32. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲	
Membrane Key 3	▼	
Membrane Key 4	▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

33. Use the Fast Reverse Key to bring the Injector Ram to the 200 ml position. Afterwards, use the Injector Hand knob to further retract the Injector Ram.

34. Confirm the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	-- ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	^	
Membrane Key 4	^ ^	
Membrane Key 5	Replace Syringe or msg. no. 01	

35. Use the Injector Hand Knob to advance the Injector Ram until 200 ml is displayed.

36. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	200 ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 14	
Membrane Key 1	^	
Membrane Key 2	^ ^	
Membrane Key 3	N/A	
Membrane Key 4	N/A	
Membrane Key 5	Replace Syringe or msg. no. 01	

Section 4.4.2.10 of system specification

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Between 0 and 200 ml

REPLACE SYRINGE invoked

Setup:

1. Move the Injector Ram to between the 1 ml and 200 ml position.
2. Press and hold Membrane Key 5 for at least one second. Release after at least one second.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	REPLACE SYRINGE IN PROGRESS, PRESS ANY KEY TO STOP or msg. no. 25	
Membrane Keys 1-5	STOP or msg. no. 08	

4. ☐ Verify that Membrane Key 1 stops the Injector Ram.
5. Restart the replace syringe process by depressing the REPLACE SYRINGE Membrane Key.
6. ☐ Verify that Membrane Key 2 stops the Injector Ram.
7. Restart the replace syringe process by depressing the REPLACE SYRINGE Membrane Key.
8. ☐ Verify that Membrane Key 3 stops the Injector Ram.
9. Restart the replace syringe process by depressing the REPLACE SYRINGE Membrane Key.
10. ☐ Verify that Membrane Key 4 stops the Injector Ram.
11. Restart the replace syringe process by depressing the REPLACE SYRINGE Membrane Key.
12. ☐ Verify that Membrane Key 5 stops the Injector Ram.
13. Restart the replace syringe process as described above.
14. Tilt the Injector out of the LOAD position but not in the RUN position.
15. ☐ Verify that tilting the Injector out of the LOAD position stops the Injector Ram.
16. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	TILT UP TO LOAD or TILT DOWN TO RUN or msg. no. 9	
Membrane Key 1-5	N/A	

17. Tilt the Injector back to the LOAD position.
18. Restart the replace syringe process as described above.
19. Tilt the Injector to the RUN position.
20. ☐ Verify that tilting the Injector to the RUN position stops the Injector Ram.

21. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

20. Tilt the Injector back to the LOAD position.
21. Press and hold Membrane Key 5 to restart the Replace Syringe process. Allow the process to complete

22. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 02	
Membrane Key 1	AUTO-INITIALIZE or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	MANUAL or msg. no. 04	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

23. Bring the Injector Ram to the 200 ml position. Press and hold Membrane Key 5 to restart the Replace Syringe process. Tilt the Injector out of the load position.

24. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

25. Tilt the Injector back to the LOAD position.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲ ▲	
Membrane Key 5	Replace Syringe or msg. no. 01	

27. Restart the replace syringe process as described above. Allow the Replace Syringe function to complete.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 02	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 04	
MEMBRANE KEY 4	N/A	
Membrane Key 5	N/A	

Section 4.4.2.11 of system specification

Injector Configuration: Tilt Status: RUN Position or Between the LOAD and RUN Position
Injector Ram Location: Replace Syringe

Setup:

1. Place the Injector in the Replace Syringe position. Cycle power on the Injector.
2. Rotate the Injector to a position between the LOAD position and the RUN position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

3. ☐ Verify that Membrane Key 1 is not active.
4. ☐ Verify that Membrane Key 2 is not active.
5. ☐ Verify that Membrane Key 3 is not active.
6. ☐ Verify that Membrane Key 4 is not active.
7. ☐ Verify that Membrane Key 5 is not active.
8. Open the syringe door.
9. ☐ Verify that the Injector now displays a syringe graphic with an arrow directing the door to be closed and the following message: "CLOSE DOOR" or msg. no. 17.
10. Close the syringe door.

SECTION 4.4.2.12 OF SYSTEM SPECIFICATION

Injector Configuration: Tilt Status: RUN Position

Injector Ram Location: Between 0 and 200 ml

Syringe loaded

Setup:

1. Press the MANUAL Membrane Key to place the Injector into manual mode.
2. Use the Arrow Membrane Keys to move the injector ram to a location that is approximately midway between the 0 ml and the 200 ml positions.
3. Rotate the Injector to the RUN position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no.12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

3. Press and hold Membrane Key 1.
4. ☐ Verify that Membrane Key 1 moves the Injector Ram forward at approximately 1 ml/sec.
5. Release Membrane Key 1.
6. ☐ Verify that when Membrane Key 1 is released the Injector Ram stops moving.
7. ☐ Verify that Membrane Key 2 is not active.
8. Press and hold Membrane Key 3.
9. ☐ Verify that Membrane Key 3 retracts the Injector Ram forward at approximately 0.5 ml/sec.
10. Release Membrane Key 3.
11. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving.
12. ☐ Verify that Membrane Key 4 toggles from Enabled and User-Disabled.
13. ☐ Verify that Membrane Key 5 is not active.
14. Press and hold the Injector Pendant switch.

15. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	CHECK OR RELEASE PENDANT or msg. no. 18	
Membrane Key 1-5	N/A	

16. Release the pendant switch.

17. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

18. Tilt the Injector out of RUN BUT NOT IN LOAD position.

19. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	Not Active	

20. Tilt the Injector back to the RUN position.

Section 4.4.2.13 of system specification

INJECTOR CONFIGURATION: Tilt Status: Between the LOAD and RUN Position
 Injector Ram Location: Between 0 and 200 ml
 Syringe loaded

Setup:

1. Tilt the Injector to the LOAD position.
2. Use the Arrow Membrane Keys to move the injector ram to a location that is approximately midway between the 0 ml and the 200 ml positions.
3. Rotate the Injector to a position that is between the LOAD and RUN position (approximately horizontal).

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	Not Active	

4. ☐ Verify that Membrane Keys 1 is Not Active.
5. ☐ Verify that Membrane Keys 2 is Not Active.
6. ☐ Verify that Membrane Keys 3 is Not Active.
7. ☐ Verify that Membrane Keys 4 is Not Active.
8. ☐ Verify that Membrane Keys 5 is Not Active.
9. Press and hold the Injector Pendant switch. Tilt the Injector to the RUN position.

10. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	CHECK OR RELEASE PENDANT or msg. no. 18	
Membrane Key 1-5	N/A	

11. Release the Injector Pendant Switch.
12. Tilt the Injector to the LOAD position. Advance the Injector ram to the 0 ml position. Tilt the Injector to the RUN position. Cycle power off and then on to the Injector.

13. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ml	
Message Area	TILT UP TO LOAD or msg. no 05	
Membrane Key 1-5	Not Active	

Section 4.4.2.14 of system specification

Injector Configuration: Tilt Status: RUN Position

Injector Ram Location: Between 1 and 200 ml

Syringe loaded

Setup:

1. Program a one valid phase into the Remote Control.
2. ☐ Verify that the EDA is IN RANGE and there is a stable baseline.
3. ☐ Verify that the Injector is tilted into the RUN position.
4. ☐ Verify that the Injector Ram is between 1 and 200 ml.
5. ☐ Verify that the Remote Control is in the STOP Mode Main Menu Screen.
6. ☐ Verify that there has been no Remote activity for two or more seconds.
7. ☐ Verify that the message "Injector Not Found" or "Remote Not Found" are not displayed.

8. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

9. Press and hold Membrane Key 1.
10. ☐ Verify that Membrane Key 1 moves the Injector Ram forward at approximately 1 ml/sec.
11. Release Membrane Key 1.
12. ☐ Verify that when Membrane Key 1 is released the Injector Ram stops moving.
13. ☐ Verify that Membrane Key 2 is not active.
14. Press and hold Membrane Key 3.
15. ☐ Verify that Membrane Key 3 moves the Injector Ram backward at approximately 0.5 ml/sec.
16. Release Membrane Key 3.

17. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving.

18. Press Membrane Key 4.

19. ☐ Verify that when Membrane Key 4 is pressed once that the EDA displays "EDA USER-DISABLED" or msg. no. 21.

20. Press Membrane Key 4 again.

21. ☐ Verify that when Membrane Key 4 is pressed once that the EDA displays "EDA ENABLED – IN RANGE" or msg. no. 22 after a five seconds of pressing the key.

22. Press and hold Membrane Key 1.

23. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

24. Release Membrane Key 1.

25. Wait two seconds and confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

26. Press and hold Membrane Key 3.

27. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

28. Release Membrane Key 3.

29. Wait two seconds and confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM	

30. Press and hold the Injector Pendant switch.

31. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	CHECK OR RELEASE PENDANT or msg. no. 18	
Membrane Key 1-5	N/A	

32. Release the pendant switch.

33. Wait two seconds and confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

34. Press the Program or msg. no. 23 key.

35. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

36. Press the Return Key on the Remote. Wait for two seconds. Confirm the following is displayed.

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

37. Disconnect the Remote communications cable at the power supply end.

38. ☐ Verify that when message "Remote Not Found" or msg. no. 24 is displayed on the Injector.

39. Confirm that the following is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

40. Reconnect the Remote communications cable at the power supply end.

41. ☐ Verify that when message "Remote Not Found" or msg. no. 24 is removed from the Injector display.

42. Wait for two seconds and confirm the following is displayed.

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM	

43. Tilt the Injector out of RUN but not in load position.

44. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	Not Active	

45. Tilt the Injector back to the RUN position.

46. Wait for two seconds and confirm the following is displayed.

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

47. Start a stopwatch. DO NOT TOUCH ANY KEY ON THE INJECTOR OR REMOTE FOR APPROXIMATELY 30 MINUTES.

48. ☐ Verify that after approximately 30 minutes, the Injector displays a screen saver with the following information: "EZEM EmpowerCT".

49. ☐ Verify that pressing any key turns the screen saver off and that the Injector displays the following:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

50. Tilt the Injector up. Press the Replace Syringe key or message no. 1 key. Allow the Replace syringe to be completed. Repower the Injector.

51. Start a stopwatch. DO NOT TOUCH ANY KEY ON THE INJECTOR OR REMOTE FOR APPROXIMATELY 30 MINUTES.

52. ☐ Verify that after approximately 30 minutes, the Injector displays a screen saver with the following information: "EZEM EmpowerCT".

53. ☐ Verify that pressing any key turns the screen saver off.

Burn-In Mode (test to be performed in English only)

For all other languages, change system back to English for testing purposes

1. Power off the Injector.
2. Press and hold membrane Key 1 and Key 3. Turn the Injector On.
3. ☐ Verify that after approximately five seconds that the Injector ram begins to move.
4. ☐ Verify that when the Injector Ram is moving at approximately 5 ml/sec.
5. ☐ Verify that the Injector display has an area from Bum cycles and that it is initially equal to zero.
6. Tilt the Injector into the three tilt positions.
7. ☐ Verify that tilting the Injector does not stop the Bum-In Mode.
8. Press any of the membrane keys.
9. ☐ Verify that pressing any membrane key does not stop the Bum-In Mode.
10. Allow the Injector ram to advance to the 0 ml position.
11. ☐ Verify that after the Injector ram reaches the 0 ml position, the Injector ram starts to retract.
12. ☐ Verify that when the Injector Ram is moving at approximately 5 ml/sec.
13. Allow the injector ram to retract to the Replace syringe position.
14. ☐ Verify that after the Injector ram reaches 0 ml position, the bum-in cycle is incremented.

Software Compatibility Testing: This test applies to software release 2.04a and higher

1. Power on an EmpowerCT Injector, EDA and Remote system with the software revision and language as stated on page 3 of this test plan.
2. ☐ Verify that the system does not display "Injector Not Found", "EDA Not Found" and "Remote Not Found".
3. ☐ Verify that the system is able to perform an injection.
4. Power off the Injector only.
5. Power on the second system. Change the Remote language to another language beside the language tested on page of the test plan. Power off the second Remote Control.
6. Disconnect the first Remote Control and attach the second Remote Control. Power on the system.
7. Utilize the table to verify that the Injector and Remote display the message listed in matrix in their appropriate language and that the system cannot be armed with the mismatch. Complete the matrix. Note for case where the Injector and Remote language are the same, tester to write N/A in the table for the verification steps. Repower Injector each language check. Note the Injector language message will be same for each part of this test.

Injector Language from Page 3 (user writes down language)	Remote Language	Injector Language Mismatch Message	Language Mismatch Message	Initial that Messages are correct	Initial that system can not be armed
	English	Language Mismatch	Language Mismatch, Please Select Desired Language.		
	German	Language MismatchG	Falsche Sprache, bitte gewünschte Sprache wählen		
	Italian	Language MismatchI	Errore di lingua, scegliere la lingua desiderata		
	French	Language MismatchF	Discordance de langue, Choisissez la langue souhaitée		
	Portuguese	Language MismatchP	Erro de idioma. Seleccione idioma deseado.		
	Spanish	Language MismatchS	Idioma incorrecto. Seleccione idioma deseado		

8. After the testing is completed, power off the Remote. Connect a Remote with software release 01.03a to the system. Power on the system.

9. Utilize the table to verify that the Injector and Remote will not allow the system to arm if the Injector is in a language beside English and the remote is software release 01.03a.

Injector Language from Page 3 (user writes down language)	Remote Language (software release 01.03a)	Initial that system can not be armed
	English	

10. Attach an English Injector software release 2.04a or later and the Remote software release 01.03a.
11. ☐ Verify that the system is able to perform an injection.

LANGUAGE MESSAGE TRANSLATION

Msg #	MESSAGE AREA	GERMAN	ITALIAN	PORTUGUESE	FRENCH	SPANISH
1	REPLACE SYRINGE	SPRITZE AUSWECHSELN	SOSTITUIRE SIRINGA	SUBSTITUIR SERINGA	REEMPLACER LA SERINGUE	SUSTITUIR JERINGUILLA
2	PRESS AUTO-INITIALIZE OR MANUAL	AUTO-INITIALISIERUNG ODER MANUELL DRUCKEN	PREMERE AUTO INIZIALIZZA O MANUALE	PRIMA INICIALIZACAO AUTOMATICA OU MANUAL	APPUYER SUR AUTO-INITIALISER OU MANUEL	PULSE INICIO AUTOMATICO O MANUAL
3	AUTO INITIALIZE	AUTO-INITIALISIERUNG	AUTO INIZIALIZZA	INICIALIZACAO AUTOMATICA	AUTO INITIALISER	AUTOINICIO
4	MANUAL	MANUELL	MANUALE	MANUAL	MANUEL	MANUAL
5	TILT UP TO LOAD	ZUM LADEN NACH OBEN KIPPEN	INCLINARE IN SU PER CARICARE	VOLTAR PARA CIMA PARA CARREGAR	TOURNER VERS LE HAUT POUR CHARGER	BASCULE HACIA ARRIBA PARA CARGAR
6	PRESS AUTO-INITIALIZE OR MANUAL OR REPLACE SYRINGE	AUTO-INITIALISIERUNG ODER MANUELL ODER SPRITZE AUSWECHSELN DRUCKEN	PREMERE AUTO INIZIALIZZA O MANUALE O SOSTITUIRE SIRINGA	PRIMA INICIALIZACAO AUTOMATICA OU MANUAL OU SUBSTITUIR SERINGA	APPUYER SUR AUTO-INITIALISER OU MANUEL OU REMPLACER LA SERINGUE	PULSE INICIO AUTOMATICO O MANUAL O SUSTITUIR JERINGUILLA
7	AUTO INITIALIZATION IN PROGRESS, PRESS ANY KEY TO STOP	AUTO-INITIALISIERUNG LAUFT, ZUM STOPPEN BELIEBIGE TASTE DRUCKEN	AUTO INIZIALIZZAZIONE IN CORSO, PREMERE UN TASTO PER INTERROMPERE	INICIALIZACAO AUTOMATICA EM CURSO, PRIMA QUALQUER TECLA PARA PARAR	AUTO-INITIALISATION EN COURS, APPUYER SUR UNE TOUCHE POUR ARRETER	INICIO AUTOMATICO EN MARCHA, PULSE CUALQUIER TECLA PARA DETENER
8	STOP	STOPP	STOP	PARAR	STOP	DETENER
9	TILT UP TO LOAD OR TILT DOWN TO RUN	ZUM LADEN NACH OBEN, ZUR AUSFUHRUNG NACH UNTEN KIPPEN	INCLINARE IN SU PER RIEMPIRE O IN GIU PER ESEGUIRE IL CICLO	VOLTAR PARA CIMA PARA CARREGAR OU PARA BAIXO PARA EXECUTAR	TOURNER VERS LE HAUT POUR CHARGER OU VERS LE BAS POUR INJECTER	BASCULE HACIA ARRIBA PARA CARGAR O HACIA ABAJO PARA EJECUTAR
10	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE	AUTO-FULLUNG ODER RUCKZUG DRUCKEN, UM DIE SPRITZE ZU FULLEN	PREMERE AUTO RIEMPIMENTO O RETRARRE PER RIEMPIRE SIRINGA	PRIMA ENCHIMENTO AUTOMATICO OU RETRAIA PARA ENCHER SERINGA	APPUYER SUR REMPLISSAGE AUTO OU RETRACTER POUR REMPLIR LA SERINGUE	PULSE RELLENO AUTOMATICO O RETIRAR PARA LLENAR JERINGUILLA
11	AUTO FILL	AUTO-FULLUNG	AUTO RIEMPIMENTO	ENCHIMENTO AUTOMATICO	REPLISSAGE AUTO	AUTORELLENO
12	WARNING: PURGE ALL AIR FROM SYSTEM	WARNUNG: SYSTEM KOMPLETT ENTLUFTEN	AVVISO: EVACUARE TUTTA L'ARIA DAL SISTEMA	AVISO: EXTRAIA TODO O AR DO SISTEMA	AVERTISSEMENT: PURGER L'AIR DU SYSTEME	ADVERTENCIA: ELIMINE TODO EL AIRE DEL SISTEMA
13	FILL VOL. = XXX ML. PRESS ADD 5 OR ADD 25 TO INCREMENT. PRESS BEGIN AUTO-FILL TO START.	FULLVOL. = XXXML. INKREM MIT 5 ODER 25 HINZUF AUTO-FULL ZUM STARTEN.	VOL RIEMP = XXXML. PREM AGG 5 O AGG 25 PER AUMENTARE. INIZIO AUTORIEMP PER COMINCIARE..	ENCH AUTO = XXXML, PRIMA +5 OU +25 P/ INCREMENTAR. PRIMA 'INICIAR ENCH.' PARA COMECAR.	VOL REMPL=XXX ML APP SUR AJOUT 5 OU AJOUT 25 PR INCREM. APP SR COMMENC AUTO REMPL POUR DEMARRER	LLENAR VOL = XXXml., PULS. +5/+25 PARA AUMENTAR PULS. INI. AUTORELLENO PARA COMENZAR
14	BEGIN FILL	FULLUNG BEGINNEN	INIZIO RIEMPIMENTO	INICIAR ENCHIMENTO	COMMENC REMLIS	INICIAR RELLENO
15	CANCEL	ABBRECHEN	ANNULLA	CANCELAR	ANNULER	ANULAR
16	AUTO FILL IN PROGRESS, PRESS ANY KEY TO STOP	AUTO-FULLUNG LAUFT, ZUM STOPPEN BELIEBIGE TASTE DRUCKEN	AUTO RIEMPIMENTO IN CORSO, PREMERE UN TASTO PER INTERROMPERE	ENCHIMENTO AUTOMATICO EM CURSO, PRIMA QUALQUER TECLA PARA PARAR	REPLISSAGE AUTO EN COURS, APPUYER SUR UNE TOUCHE POUR ARRETER	RELLENO AUTOMATICO EN MARCHA, PULSE CUALQUIER TECLA PARA DETENER
17	CLOSE DOOR	TUR SCHLIESSEN	CHIUDERE SPORTELLLO	FECHAR PORTA	FERMER LA PORTE	CIERRE ORIFICIO DE ENTRADA
18	CHECK OR RELEASE PENDANT	HANDSCHALTER PRUFEN BZW. FREIGEBEN	CONTROLLARE O RILASCIARE LA PULSANTIERA	VERIFICAR OU LIBERTAR COMUTADOR	VERIFIEZ OU RELACHEZ L'INTERRUPTEUR INJECT/PAUSE	COMPRUEBE O LIBERE EL COLGANTE

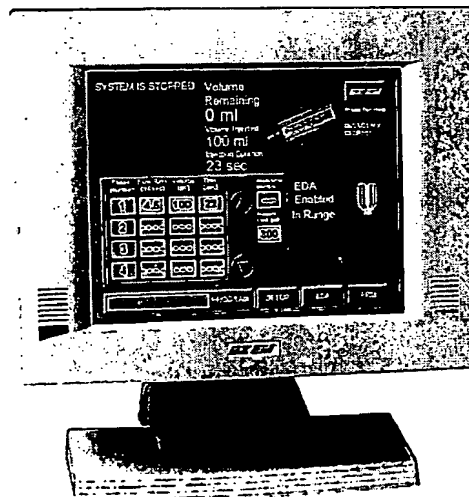
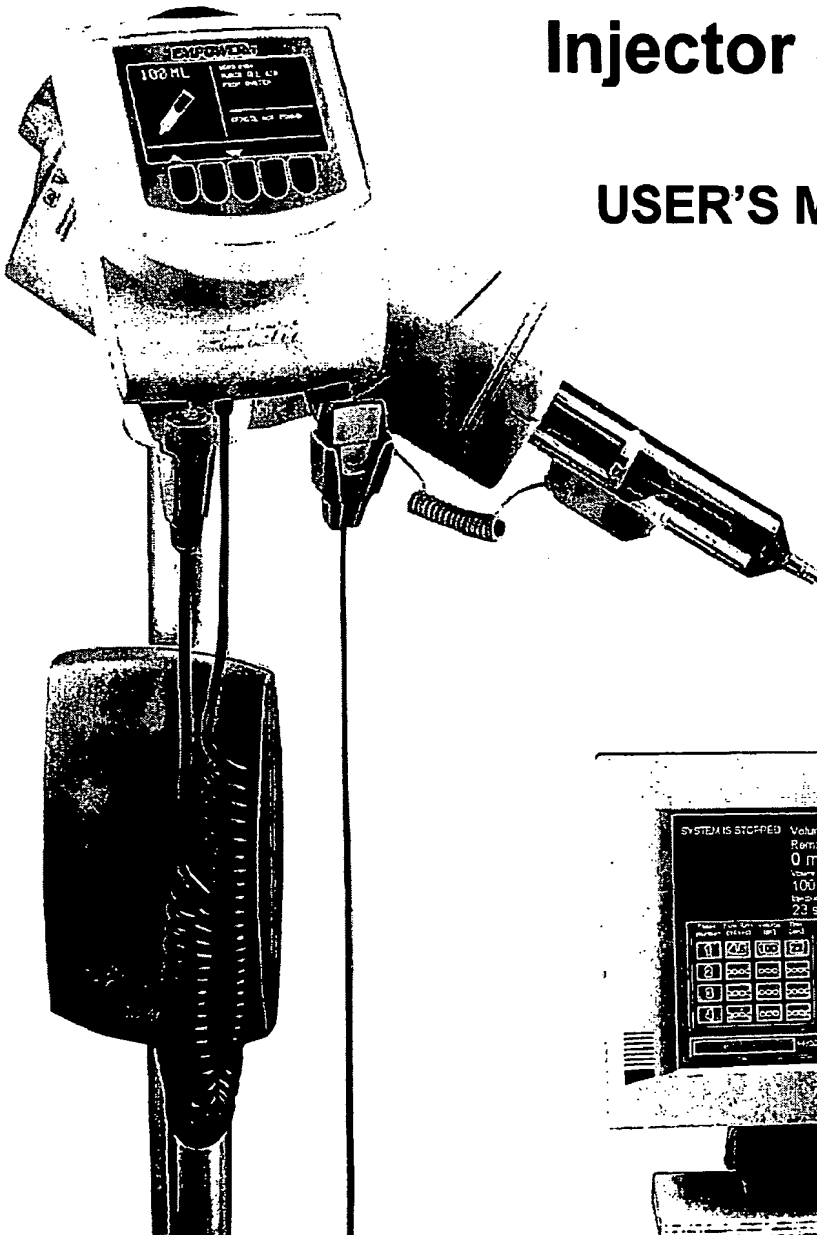
Msg #	MESSAGE AREA	GERMAN	ITALIAN	PORTUGUESE	FRENCH	SPANISH
19	WARNING: PURGE ALL AIR FROM SYSTEM, PRESS ARM TO CONTINUE	WARNUNG: SYSTEM KOMPLETT ENTLUFTEN, DANN BEREIT DRUCKEN, UM FORTZUFAHREN	AVVISO: EVACUARE TUTTA L'ARIA DAL SISTEMA, PREMERE CARICA PER CONTINUARE	AVISO: EXTRAIA TODO O AR DO SISTEMA, PRIMA ARMAR PARA CONTINUAR	AVERTISSEMENT: PURGER L'AIR DU SYSTEME, APPUYER SUR ARMER POUR CONTINUER	ADVERTENCIA: ELIMINE TODO EL AIRE DEL SISTEMA, PULSE ARMAR PARA CONTINUAR
20	ARM	BEREIT	CARICA	ARMAR	ARMER	ARMAR
21	EDA USER- DISABLED	EDA DEAKTIVIERT	UTENTEEDA DISATTIVATO	EDA DESAC POR UTIL.	EDA DÉS. PAR UTIL.	EDA DESAC P USUARIO
22	EDA IN RANGE	EDA IM BEREICH	EDA IN RANGE	EDA DENTRO LIM	EDA DANS PLAGE	EDA EN ESCALA
23	PROGRAM	PROGR.	PROGRAM	PROGRAM	PROGRAM	PROGRAM
24	REMOTE NOT FOUND	FERNSTEUERUNG NICHT GEFUNDEN	TELECOMANDO NON TROVATO	TELECOMANDO NÃO ENCONTRADO	TELECOMANDE INTROUVABLE	REMOTO NO ENCONTRADO
25	REPLACE SYRINGE IN PROGRESS, PRESS ANY KEY TO STOP	SPRITZE WIRD GEWECHSELT, ZUM STOPPEN BELIEBIGE TASTE DRUCKEN	SOSTITUZIONE SIRINGA IN CORSO, PREMERE UN TASTO PER INTERROMPERE	SUBSTITUIR A SERINGA EM CURSO, PRIMA QUALQUER TECLA PARA PARAR	REMPLECE LA SERINGUE EN COURS, APPUYER SUR UNE TOUCHE POUR ARRETER	SUSTITUIR JERINGUILLA EN MARCHA, PULSE CUALQUIER TECLA PARA DETENER

EZEM[®]

EMPOWER^{CT}_{CT}

Injector System

USER'S MANUAL



CE0086



Visualize a healthier world.

All technical specifications, systems approvals and regulatory requirements are found in Appendix C.

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In the United States, E-Z-EM can be contacted at: In the EU, E-Z-EM can be contacted at:

E-Z-EM, Inc.
717 Main Street
Westbury, New York 11590-5021
Phone: (516) 333-8230
Toll Free: (800) 544-4624
Fax: (516) 333-8278
www.ezem.com

E-Z-EM, Ltd.
Avonbury Business Park
Bicester
Oxfordshire
OX26 2UB
United Kingdom
Phone: 011 44 1869 366900
Fax: 011 44 1869 366999

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SECTION 1: IMPORTANT WARNINGS, CAUTIONS, AND LABELS

Before using the EmpowerCT Injector System, please read the following Sections carefully and be certain you understand them fully. Failure to do so may result in damage to the Injector System or other equipment, or in the serious injury of the patient or technologist. If you have any questions after reading the following Sections, please contact E-Z-EM Customer Service.

1.1 Warnings



The hazards referred to in this Section can seriously injure a patient or technologist. Read this Section carefully.

- The sole purpose of the EmpowerCT Injector System is to intravenously administer iodinated contrast solutions into human patients who are undergoing diagnostic exams for Computed Tomography. It is not intended for any other use. **DO NOT** use this equipment for any application other than its expressed purpose.
- This equipment is not for use in chemotherapy, drug infusion, or any other application for which it is not indicated.
- The EmpowerCT Injector System must be used properly to prevent the risk of an air embolism. Always fill the syringe with the Injector pointing fully upward. **When the syringe has been filled with the desired volume, all the air should be purged from the syringe and coiled tubing with the Injector still in the fully vertical position. Failure to do so may lead to serious injury and /or death.**
- In the event of a system malfunction, immediately turn off the EmpowerCT Injector System and quickly disconnect the patient from the unit. Confirm that the system malfunction has been repaired before reconnecting the patient. Turn the system on, arm the injector and perform a test injection. If the system shows no further malfunction, reconnect the patient. If a fault message still exists and cannot be corrected and/or the injector is still malfunctioning, **DISCONTINUE USE** of the EmpowerCT Injector System until the problem is properly identified and solved. Contact E-Z-EM for further assistance.
- Never use the reverse or fast reverse buttons on the EmpowerCT Injector System (i.e., those buttons with downward pointing arrows shown above them), nor the Replace Syringe button on the Injector System, while the EmpowerCT Injector System is connected to the patient.
- Exercise extreme caution when setting the flow rate on the Remote Control and/or the Injector Controller so as not to create an inadvertently high flow rate injection. **PATIENT INJURY CAN RESULT FROM HIGH FLOW RATE VENOUS**

SECTION 1: IMPORTANT WARNINGS, CAUTIONS, AND LABELS

INJECTIONS. Be sure to review all program parameters and injection settings prior to arming and running the injector.

- The EmpowerCT Injector System is not MRI compatible and must not be used in magnetic resonance imaging (MRI) studies. Portions of the EmpowerCT Injector System will respond dangerously to the very high magnetic fields associated with MRI scanners.
- A risk of explosion exists if the EmpowerCT Injector System is used in the company of flammable anesthetics. It should never be operated when any flammable gases are present. This equipment is not suitable for use when a **FLAMMABLE ANESTHETIC MIXED WITH AIR or OXYGEN or NITROUS OXIDE** is present.
- The EmpowerCT Injector System has been proven to work properly with E-Z-EM supplies. To prevent the risk of incompatibilities and equipment failures during procedures, use only syringes and extravasation detection patches supplied directly by E-Z-EM or its authorized distributors.
- After the FastLoad™ syringe has been filled with contrast media it should be used within a few hours. Once exposed to air, bacterial growth may occur. Always follow the contrast media manufacturer's labeling for handling, loading, use, storage and disposal of their product.
- To prevent transmission of infection, observe aseptic techniques when handling an extravasation detection patch, contrast media, or any equipment or materials that contain or conduct the contrast media, including syringes, fill tubes, and intravenous administration sets. Never reuse any of these single-use items. Discard these disposable items using proper procedures for bio-hazardous waste.
- To assure sterility, as well as to prevent spills or damage to the equipment, always inspect the packaging of every syringe and the syringe itself to verify that there are no broken seals or other signs of damage. If such conditions exist, do not use the syringe.
- Always inspect the foil packaging of every extravasation detection patch and the patch itself to verify that there are no signs of damage to either. If such conditions exist, do not use the patch.
- Spilled fluid can result in the possibility of electrical shock. Do not allow contrast media or other fluids to spill over the EmpowerCT Injector System. Do not immerse any parts of the EmpowerCT Injector System when cleaning. This could create a conductive path between metallic parts of the EmpowerCT Injector System and the patient.
- Use the EmpowerCT Injector System only when connected to a proper electrical source. Plug the EmpowerCT Injector System and Remote Control directly into a grounded, hospital-grade electrical outlet. Do not use an extension cord. Do not use an adapter to plug the EmpowerCT Injector System or Remote Control into a two-pronged, non-grounded outlet. Replace any worn or frayed wires immediately.

- The EmpowerCT Injector System, as well as any other electrical equipment attached to the patient and/or catheter, must be electrically isolated or properly grounded to prevent possible electrical shock.
- Attempting to open the EmpowerCT Injector System or Remote Control can also result in electrical shock. Do not open or attempt to repair or modify either component. These units contain no user-serviceable parts. Only authorized E-Z-EM service personnel should perform servicing of internal parts.
- Administering IV contrast with a CT Injector poses the risk of extravasation. As with any procedure that involves intravenous injection of a substance, proper technique can substantially reduce the incidence of extravasation. While the specific technique must always be established by the attending physician, suggested precautions when using the EmpowerCT Injector System can be found in Section 2.2.2 (Prepare the Patient).
- Always instruct the patient to immediately notify the CT personnel of any pain or change in feeling that is experienced during the procedure.

1.2 Cautions

The hazards referred to in this Section can result in equipment damage or failure, although they are unlikely to result in serious injury.

- Connect the EmpowerCT Injector System only to an electrical source of the proper voltage and frequency as specified in Section 8.1. If an incorrect voltage is used, the Injector System may be damaged when it is turned on.
- When retracting the syringe plunger with the EmpowerCT Injector System during contrast filling or after the end of an injection, do not let a vacuum build in the syringe by occluding the J-Tube or patient coiled tubing. Failure to let the syringe properly vent when retracting the syringe plunger can cause the plunger to re-coil forward when the Injector ram reaches the replace syringe position.
- Rx only (USA)
- The use of **accessory** equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
 - use of the accessory in the **patient vicinity**.
 - evidence that the safety certification of the **ACCESSORY** has been performed in accordance to the appropriate IEC 60601-1 and/or IEC/EN 60601-1-1 harmonized national standard.

1.3 Labels

The symbols used on the EmpowerCT Injector System include the following, signifying warnings, cautions, and notes:



Patient Applied Part, Extravasation Detection Accessory,
Degree of protection against electric shock, Type CF



Patient Applied Part, Injector Head, Degree of protection
against electric shock, Type BF.



Attention! Read the user's manual before using.



Potential equalization.



With respect to electric shock, fire, mechanical and other
specified hazards, only in accordance with UL 2601-1
and CAN/CSA C22.2 No.601.1 medical equipment
34MB.



Compliance, European directive 93/42/EEC, Medical
Device Directive

SECTION 2: BASIC OPERATING PROCEDURES

2.1 Introduction

This manual describes the many features of the EmpowerCT Injector System. This Injector System is intended to deliver venous-side iodinated X-ray contrast media at low pressure for use in conjunction with a computed tomography (CT) scanner. For instructions on the use of your particular scanner and its other related equipment, please consult the manuals provided with those devices or contact their manufacturers.

Shown below are the components of the EmpowerCT Injector System that are referred to in this manual.

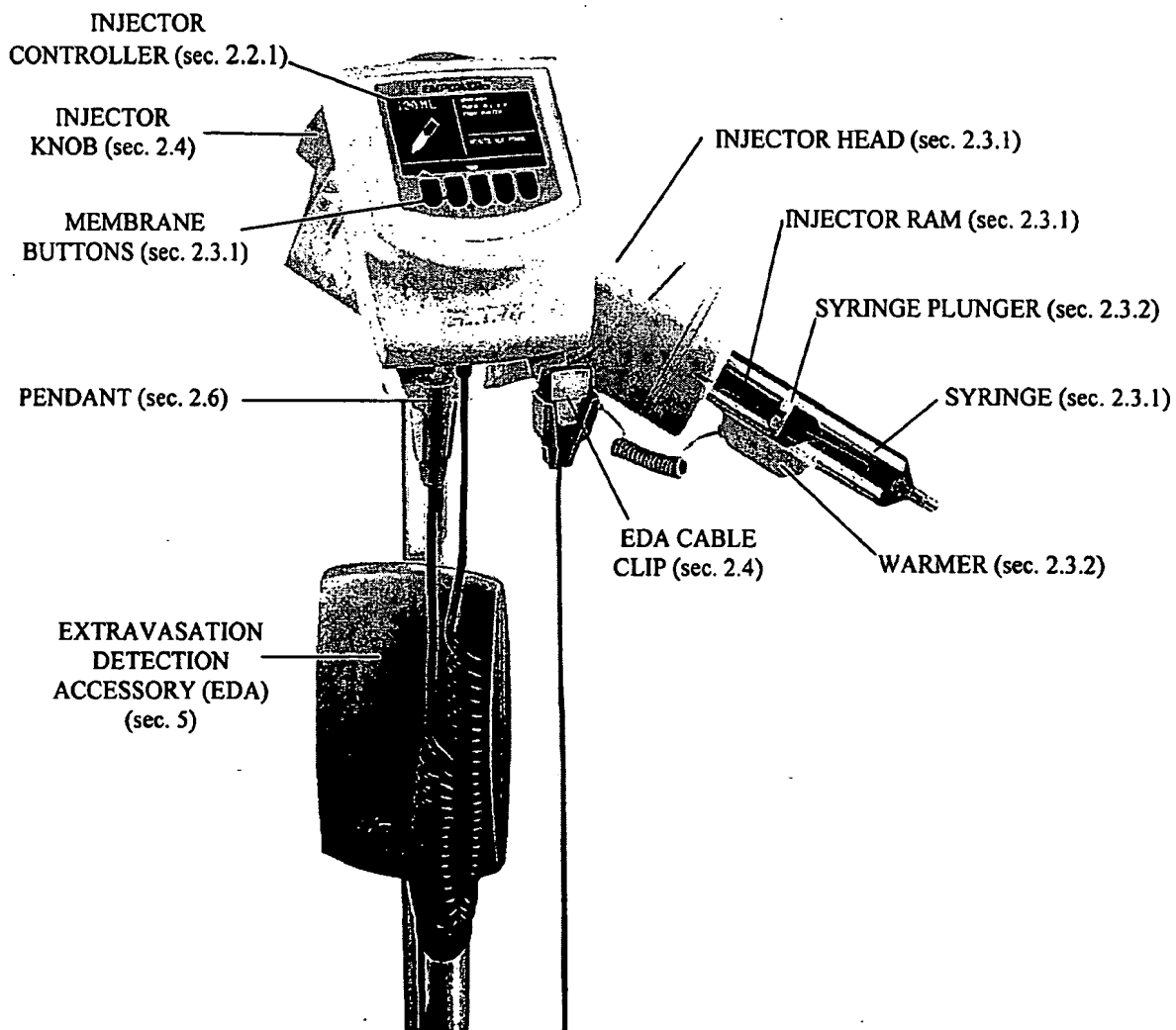


Figure 2.1 EmpowerCT Injector System

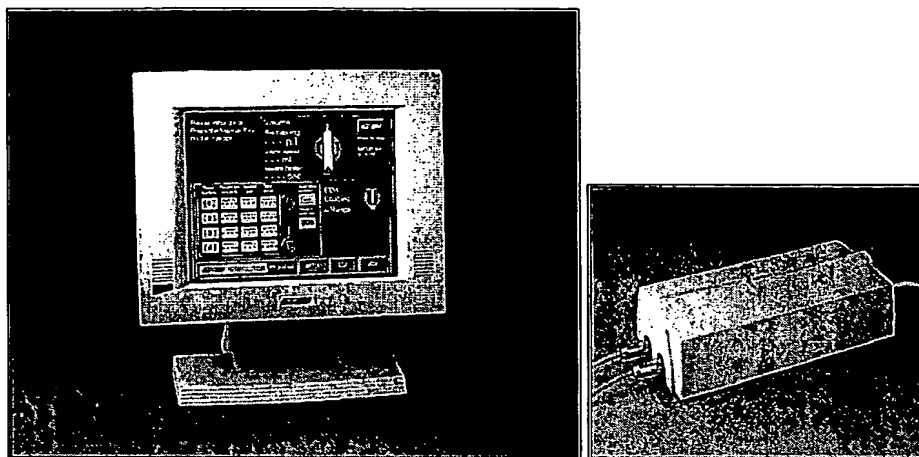


Figure 2.2 Remote Control (sec. 2.5) and Power Supply (sec. 7.1.4)

The EmpowerCT Injector System has two primary components: the Injector System, which includes the Injector with Injector controller, EDA, connection cables, and syringe warmer and the Remote Control. There is also a power supply, which connects the two main components. All that is necessary to perform an injection utilizing these components is to follow the six steps below, which are described in more detail in the Sections that follow:

1. Prepare the patient, equipment, and interface between them.
2. Load the syringe and fill with contrast media.
3. Remove all air from the syringe and tubing.
4. Program the Remote Control.
5. Arm, and then run the injection.
6. Disconnect patient and unload the syringe.

2.2 Prepare the Patient and Equipment

In this step, it is verified that the equipment is powered on and that the patient is prepped.

2.2.1 Power On the Equipment

1. Beginning in the control room, verify that the Remote Control's power is on. If it is, the screen will be displaying graphics associated with one of its operating interfaces, or a moving screen saver logo. If nothing is displayed, flip the rocker switch on the right underside of the Remote Control.

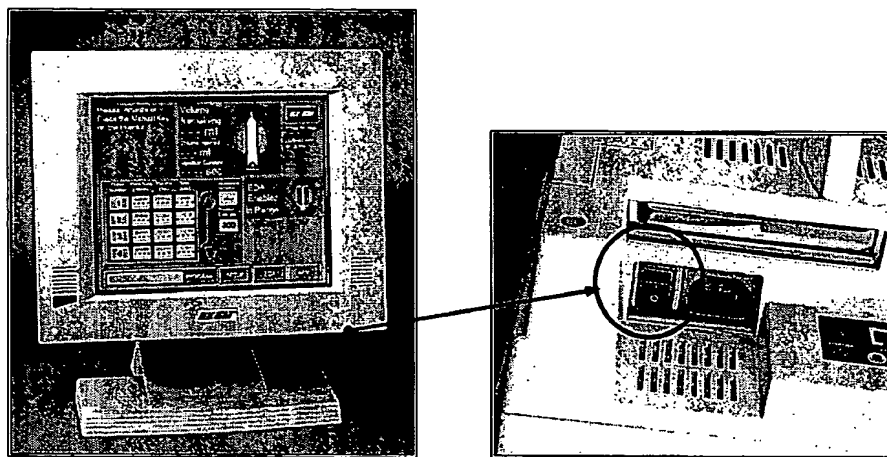


Figure 2.3 Remote Control Power Switch

2. Go to the Injector Controller, and verify that its power is on as well. If it is, the screen will be displaying its graphics. If nothing is displayed, flip the rocker switch on the right underside of the Injector Controller's screen.

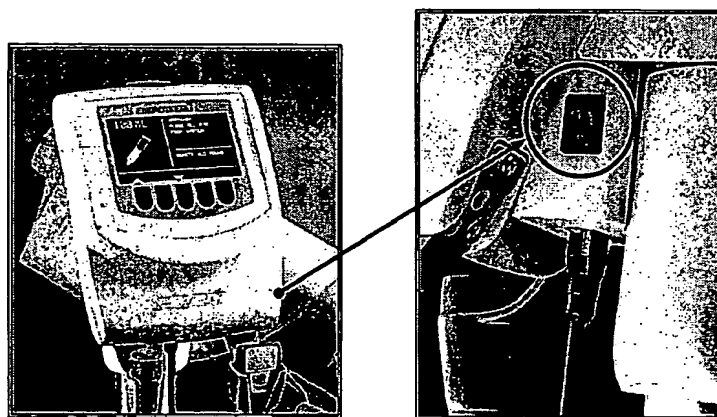


Figure 2.4 Injector Controller's Power Switch

2.2.2 Prepare the Patient

1. Verify that the patient has an intravenous catheter inserted properly.



To minimize the possibility of an extravasation we suggest the following:

- Use a catheter that is 20 gauge or greater in the largest vein possible. E-Z-EM recommends an Angiocath®, Angio-Set® or equivalent. (Angiocath® and Angio-Set® are registered trademarks of Becton Dickinson and Company.)
 - Minimize the effects of patient movement by taping the catheter firmly to the patient's skin. Use of an Angiocath-type butterfly permits easy insertion and secure taping.
 - The forearm is the preferred location for venipuncture. This position permits the arms to be placed over the head during body scans without the danger of kinking either the catheter or tubing. Use of a 60-inch/1.5-meter, coiled, low-pressure tube also reduces the motion effects associated with table movement.
 - Do not use catheters that are kinked or that have been kinked.
 - If a patient presents with one or more indwelling intravenous lines, do not assume that the intravenous set is acceptable for use with the EmpowerCT Injector System. If possible, place a new intravenous line.
 - Central venous lines and heparin-locks are not recommended.
 - To augment clinical monitoring during contrast media injection and to help detect potentially serious extravasations, E-Z-EM recommends use of the Extravasation Detection Accessory (EDA) in conjunction with the EmpowerCT Injector System.
2. If you have E-Z-EM Extravasation Detection Accessory (EDA), please refer to Section 5 for proper use of the EDA.

2.3 Load the Syringe and Fill with Contrast Media

Note: Use Only E-Z-EM FastLoad™ Syringe Pack (Cat.# 6720)

In this step, the Injector System is prepared for the syringe, which is loaded and filled with contrast.

If a syringe is still loaded from a prior procedure, unload the old syringe by following the instructions that begin in Section 2.7 of this manual.

2.3.1 Prepare the Injector System for a New Syringe

1. Tilt the Injector head into the upright position as shown in Figure 2.5.
2. The words **REPLACE SYRINGE** should appear in the lower right corner of the Injector Controller's display. Press and hold down the membrane panel button beneath this label until the word **STOP** is displayed. The Injector Controller will beep twice. Release the button and wait for the Injector ram to fully retract and stop.

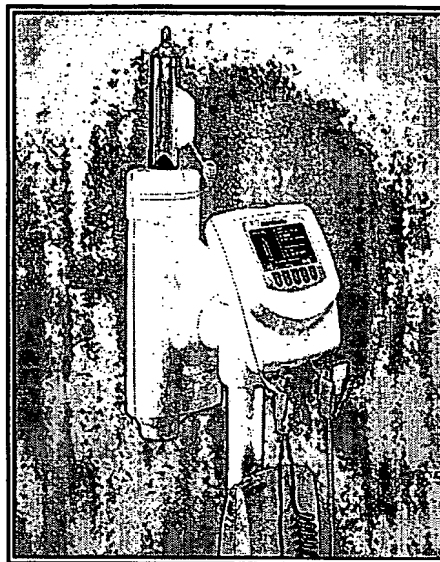


Figure 2.5 Injector Head in Upright Position

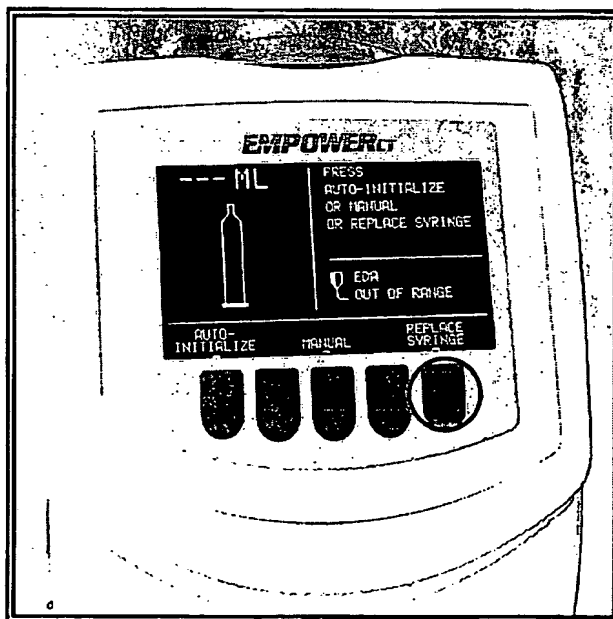


Figure 2.6 Replace Syringe Button

3. The words **AUTO-INITIALIZE** will then be displayed in the lower left corner of the Injector Controller's screen. Open the syringe door as shown in Figure 2.7.

2.3.2 Load a New Syringe

1. With the syringe door open, insert the lip of a newly opened syringe into the groove in the syringe housing. Use care when inserting into groove to prevent the syringe's releasing fingers from being damaged.
2. Fully close the syringe door. Verify that the Injector Controller's screen is not displaying the message **DOOR OPEN**. The door will lock itself automatically during the next step.

Locate the words **AUTO-INITIALIZE** at the lower left of the Injector Controller's screen as shown in Figure 2.9. Press the membrane button beneath these words, and hold it down until they are replaced by the message **STOP**; then release the button. The Injector Controller will beep twice, and the Injector ram will advance the syringe plunger to the distal end of the syringe. At that point the volume remaining display will indicate 0 mL. As the Injector ram advances from the replace syringe position, the syringe door will automatically lock.

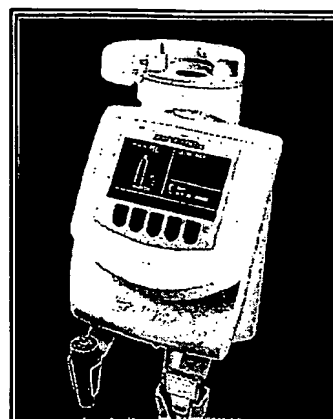


Figure 2.7 Open Syringe Door

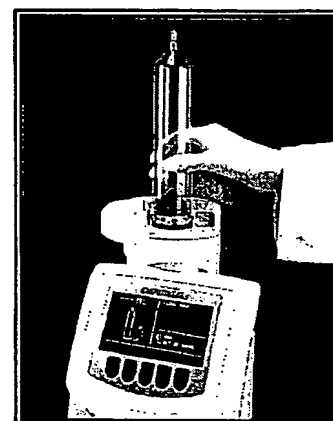


Figure 2.8 Syringe in Groove

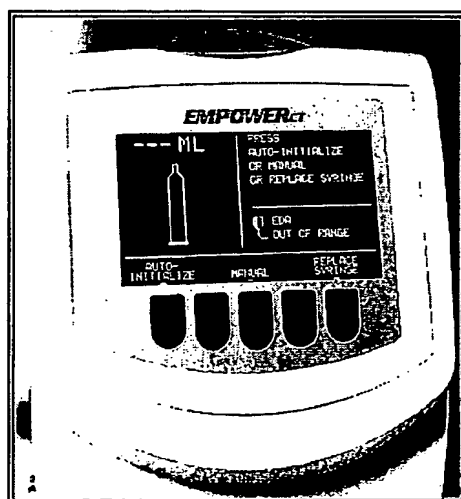


Figure 2.9 Auto-Initialize and Manual

As an alternative to **AUTO-INITIALIZE**, as well as a variety of other automated functions, it is also possible to manually control the movement of the Injector ram and syringe plunger using the button located beneath the word **MANUAL** at the middle of the bottom of the Injector controller's screen (Figure 2.9).

After you push **MANUAL**, the Injector Controller icons used for forward and reverse manual positioning of the Injector ram will appear directly over the row of membrane buttons.

From left to right, the movement is slow forward (i.e., advancing the syringe plunger slowly), fast-forward, slow reverse (i.e., retracting the syringe plunger slowly), and fast reverse (Figure 2.10). To achieve the same goal as **AUTO-INITIALIZE**, press and hold down the fast forward button until the ram and plunger stop moving.

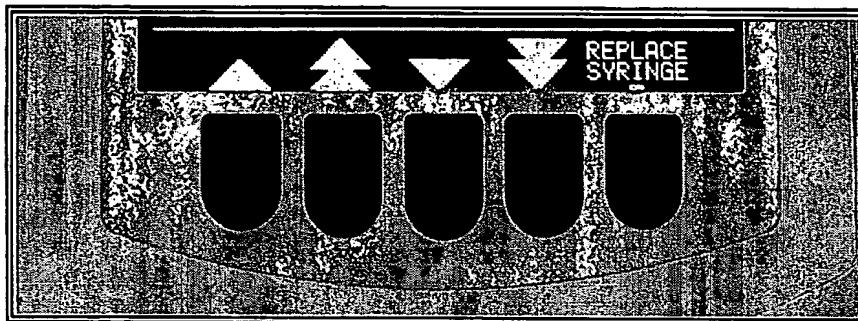


Figure 2.10 Injector Controller with Manual Controls

When using **MANUAL**, the volume remaining display on the Injector Head and Remote Control will automatically start displaying this parameter as soon as the injection ram is located anywhere within its 200 mL operating range. At that point it is possible to tilt the Injector head down to its **run** position, and then proceed to **arm** and **run** an injection. This feature provides the user the ability of not having to empty the contents of a syringe should the Injector head need to be re-powered, or have its injection ram brought back to the Replace Syringe position.

3. Attach the warmer to the syringe as shown in Figure 2.11.

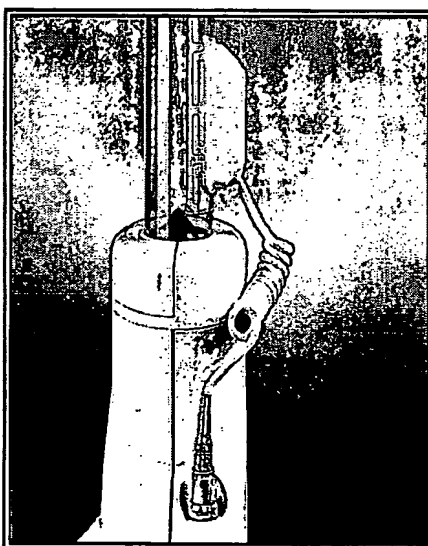


Figure 2.11 Attached Warmer

2.3.3 Fill the Syringe with Contrast Media

1. Using aseptic technique, open a bottle of pre-warmed contrast media.
2. Attach the short end of the supplied J-tube to the open end of the syringe (Figure 2.12).
3. Insert the other end of the J-tube into the bottle of contrast media (Figure 2.12).
4. Determine the amount of contrast media to load into the syringe. Include several mL to be expelled when purging air from the system prior to making the patient connection.

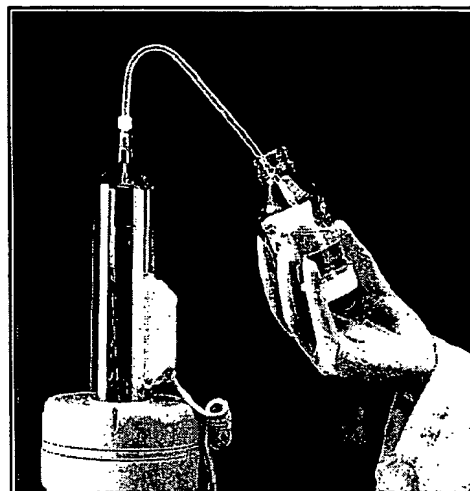


Figure 2.12 J-Tube and Contrast Bottle

5. As shown in Figure 2.13, press the membrane buttons until the desired fill volume of contrast media is displayed near the upper right corner of the screen. This value will be maintained for subsequent injections or until it is overridden by further changes to the **AUTO-FILL** function.

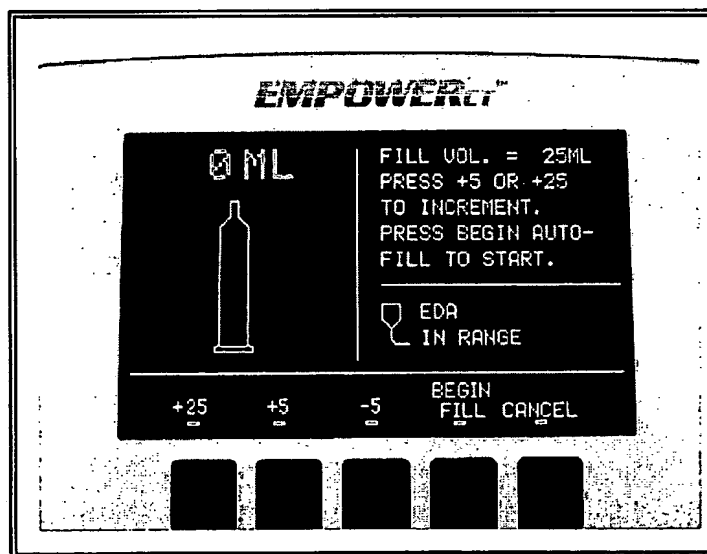


Figure 2.13 Auto-Fill

- When the desired volume of contrast media is displayed on the screen, press and hold down the membrane button associated with **BEGIN FILL** (Figure 2.13) until they are replaced by the word **STOP** (Figure 2.14). The Injector Controller will beep twice, and the syringe plunger will begin to retract. Contrast media will then be withdrawn from its bottle into the syringe. When holding the contrast media bottle maintain its orientation such that the end of the J-Tube does not create a vacuum with the contrast media bottle's bottom surface. Creating a vacuum will produce unwanted cavitation bubbles in the contrast media that will be difficult to purge. Additionally, relieving the vacuum after filling could cause unwanted contrast media spillage.

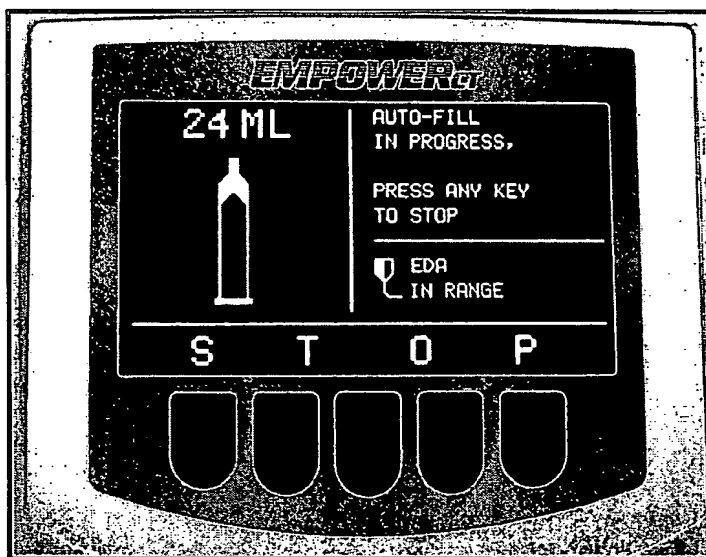


Figure 2.14 Auto-Fill

When the syringe plunger stops moving at the completion of **AUTO-FILL**, controls for manually advancing and retracting the injection ram will appear on the display. These buttons can be used to manually withdraw additional contrast at the completion of **AUTO-FILL** should it be desired.

- Remove the J-tube from the syringe and the bottle of contrast media.

2.4 Remove All Air from the Syringe and Tubing



Warning, failure to carefully follow these instructions in this step may result in serious injury and/or death. If you do not completely understand these instructions, do not proceed.

1. With the Injector head in the upright position, connect the coiled tubing to the syringe. Temporarily remove the end cap from the patient end of the coiled tubing.
2. Use the slow and fast forward membrane buttons to advance the injection ram and expel all air from the syringe and coiled tubing. At the lower left of the Injector Controller's screen there is a single upward pointing arrow, which means "slow forward." As previously described in Section 2.3.2, the button beneath this will cause the Injector System to slowly advance the syringe plunger, in this case displacing all the air out of the syringe and coiled tubing. Press and hold this button down until there is no air left in the coiled tubing or syringe. (Alternatively, the Injector knob on the back of the Injector can be used to move the syringe plunger manually.)



*Figure 2.15 Attaching Coiled Tubing
(Note: The Injector is not completely upright)*

If bubbles should adhere to any part of the syringe or tubing, gently tap your fingers on that area to dislodge the bubbles.

3. **Verify that all air has been removed from the syringe and the coiled tubing. If you have any doubts about the presence of air, do not proceed.** Either use the slow forward button or Injector knob to expel more contrast media until the air is gone.
4. Once the contrast media has completely filled the coiled tubing and a small meniscus is present at the patient end of the tube, recap and use holding slots (Figure 2.15) on Injector door housing as required.
5. Attach the free end of the coiled tubing to the patient's catheter. If an extravasation detection patch is being used, position the tubing adjacent to the EDA cable.

SECTION 2: BASIC OPERATING PROCEDURES

6. Tilt the Injector fully downward toward whichever side is most convenient. It will be displayed as tilted down on both the Injector Controller's screen and the Remote Control.

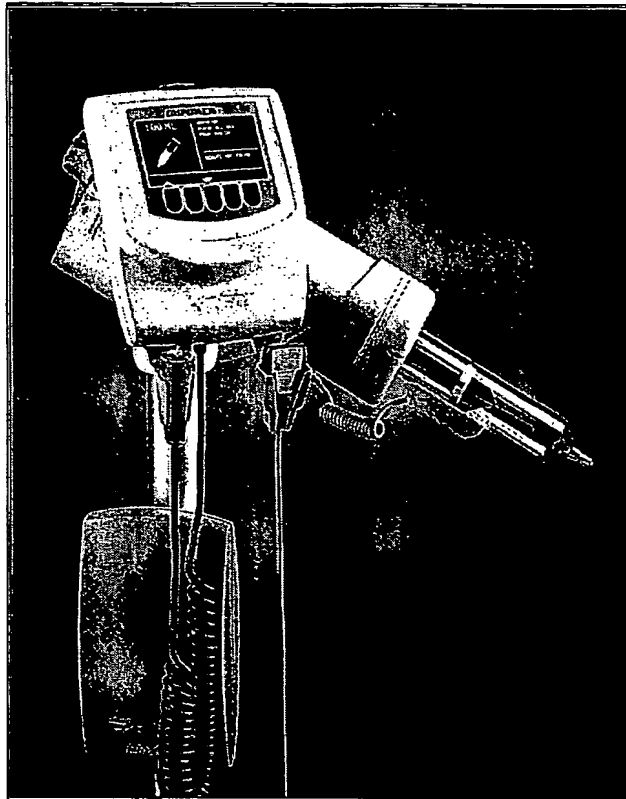


Figure 2.16 Injector Tilted Down

7. If an extravasation detection patch is to be applied, refer to Section 5 for proper instructions.

The Injector System is now ready for the injection.

2.5 Program the Remote Control

In this step, the Remote Control is prepared for the injection.

2.5.1 Reading a Program

An injection program is a series of injection phases displayed on the Remote Control's screen as a numbered list of flow rates, volumes, and durations. For example, using the information shown in Figure 2.17 below, the Injector System would inject 20 mL at 1.5 mL/sec for 13 seconds, 10 mL at 2.0 mL/sec for 5 seconds, pause until instructed to proceed, then conclude with 30 mL at 3.0 mL/sec for 10 seconds.

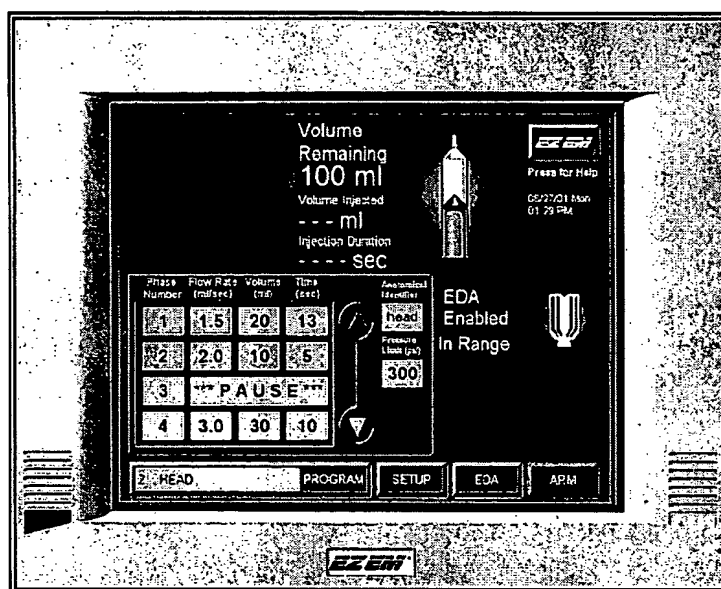


Figure 2.17 A Program

The entire injection is the "program." Each of the individual steps within the program is an "injection phase." When the injection is run, the Injector System will execute each of the phases, sequentially, and then stop automatically.

2.5.2 Removing an Existing Program from the Main Screen

Shown below in Figure 2.18 is the Main Screen of the EmpowerCT Remote Control. If at any time you have difficulty using or understanding this or any screen on the Remote Control, press the E-Z-EM logo at the top right corner of the screen to access the Remote Control's built-in Help system (see section 4.4).

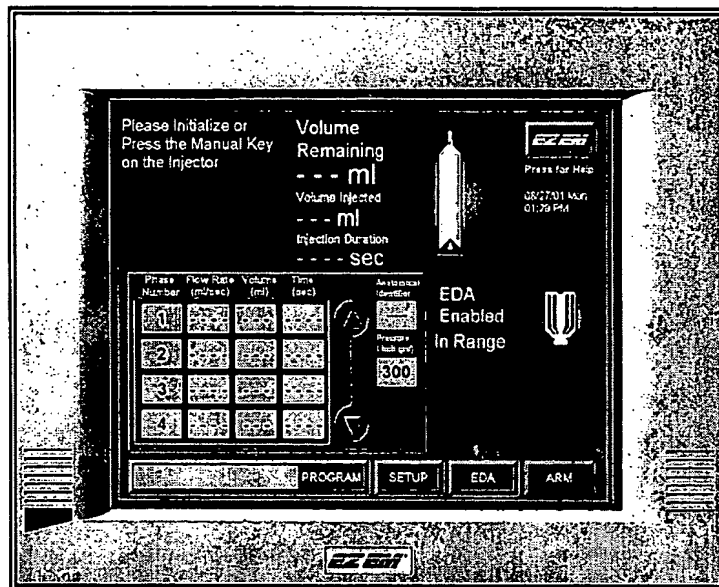


Figure 2.18 Main Screen

The table in the lower left quadrant of the screen is the program, as described in the preceding Section. In this photo, a four-phase program has already been entered. Unless this happens to be the desired program, delete all of the existing phases and then start again.

To remove an existing program from the Main Screen:

1. Press on the number 1 on the screen in the table's **Phase Number** column. The Remote Control uses a touchscreen display. When the Remote Control has recognized pressing on a button, it will beep.
2. After pressing directly on the number 1 in the **Phase Number** column, a small pop-up data entry window is displayed.

This window has three touchscreen buttons. Press the button marked **DELETE**. The first phase of the existing program will be deleted, and the remaining phases will move up in the table and be renumbered.

3. Repeat steps 1 and 2 until the table is completely blank except for the phase numbers.

2.5.3 Enter a New Program

A new program must be created phase-by-phase, beginning with phase 1 in the first row of the table. For each phase, a flow rate and a volume must be specified; then the Remote Control will calculate the time to complete that phase. Repeat steps 1 through 6 for each phase to be created, beginning with phase 1 and working down through the table to a maximum of 8 phases.

1. For the current phase being programmed, press the flow rate field. A Flow Rate Range data input pop-up window will appear as shown in Figure 2.19.

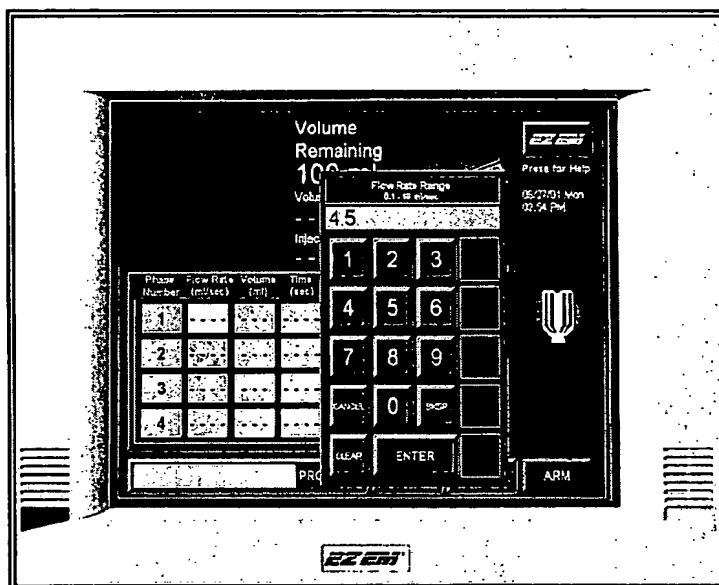


Figure 2.19 Flow Rate Range

2. Enter the desired flow rate in mL/sec. Enter only the digits. The Remote Control will automatically add one decimal place to whatever is typed (e.g., if you type "100", the Remote Control will make this "10.0"). If any mistakes are made, press the BKSP ("backspace") button to erase them one character at a time.
3. When the desired flow rate has been specified in the Flow Rate Range window, press **ENTER**. The window will disappear. The Main Screen will return with the specified flow rate entered into the table.
4. Press on the volume field that is to be programmed. A Volume Range data input pop-up window will appear, similar to the Flow Rate Range window as shown in Figure 2.20.
5. Enter the desired volume in mL, similar to the way you entered the flow rate. When finished, press **ENTER**.
6. To have the EmpowerCT Injector System pause between programmed injection phases, enter a phase that reads ***** PAUSE ***** at the point where the injection should pause. To do this, press directly on the number of the phase to have as a pause, then in the resulting window press **PAUSE** and **ENTER**.

2.6 Perform the Injection

When the patient, EmpowerCT Injector System, and program have all been prepared, performing the injection is simple.

1. If you do not have an EDA, go to step 2.

If the EDA message area on the Injector and Remote displays **EDA Enabled Out of Range**, the EDA is indicating that something is not properly set up with the extravasation detection patch or the EDA cable. Check the connections carefully. The injection cannot proceed unless the problem is rectified or the EDA is user-disabled.

If you will not be using the EDA during this injection, press the **EDA** key on the Injector or Remote Control. The EDA message area on the Injector and Remote will display the message **EDA User-Disabled**.

2. When everything is ready, press the **ARM** button at the lower right of the Remote Control's screen, which will now be green instead of blue. In addition, there will be an **ARM** key on the Injector. The **ARM** key on the Injector will only be displayed if there are four or less programmed phases on the Remote Control.
3. If you have an EDA, but have previously elected that it will not be used during this injection, press the EDA key on the Injector or Remote one more time as a final acknowledgement to continue without this accessory as part of the **arm** process.
4. In the **arm** mode, the Empower CT Injector System offers the opportunity to review the programmed parameters one more time. If ready to proceed, either press **RUN** on the Injector or Remote or press the pendant switch. Alternatively, to return to the Main Screen press **STOP**.

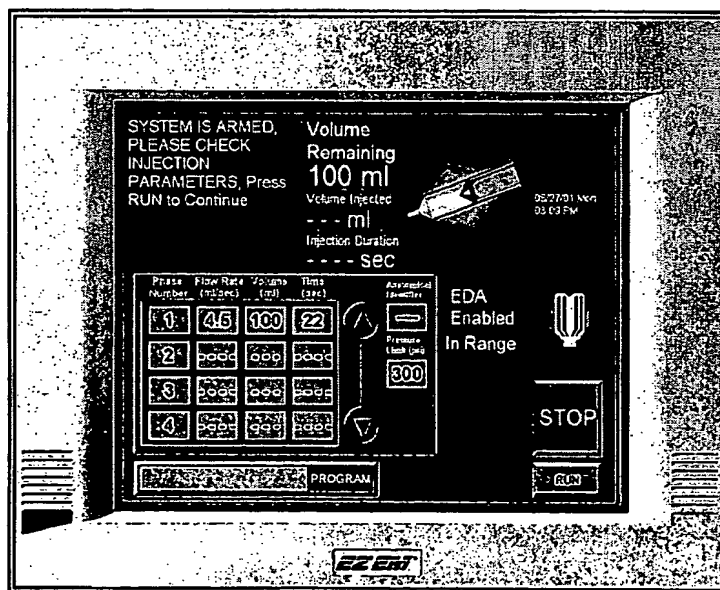


Figure 2.20 Arm

SECTION 2: BASIC OPERATING PROCEDURES

The injection will begin. The Remote Control will display the progress of the injection as it runs. You can adjust the flow rate of the current phase while it is in progress by pressing and holding down the up or down (i.e., increase or decrease, respectively) arrow above or below the flow rate in the upper right corner of the screen or the far left (decrease) and far right (increase) keys on the Injector Controller. **Use caution when manually adjusting the flow rate during an injection.**

5. To pause the injection, touch the Remote Control's screen anywhere except in the "flow rate" box at the upper right. The system will also pause automatically if the EDA detects a possible extravasation condition, or if you press any one of the middle three buttons below the Injector Controller's screen, or if you press the button on the pendant attached to the Injector Controller or Remote Control. To resume the injection after a pause, press RUN key on the Injector or Remote Control or press the button on the pendant.



6. The injection will end automatically when it has run through the complete program. In either case, the Main Screen will be displayed when the program has ended.

Pressure limiting and over-pressure messages may occur due to simultaneous selection of a high flow rate and a low-pressure limit value, or because of a blockage in the fluid path. If either of these messages is displayed, check the fluid path. If there are no blockages, adjustments may need to be made to the flow rate or pressure limit in accordance with physician's orders.



If during an injection pressure limiting causes the contrast media delivery to remain at a sustained flow rate less than the programmed flow rate, the user is notified by an acknowledgment tone and display on the Remote Control. Unless there is some intervention by the clinician, such a pressure-limited injection will generally continue until completion. The decision to continue or stop the injection for this or any reason rests with the clinician.



In the event of a system malfunction or a patient complication during an injection, press the STOP button immediately.



2.7 Unload the Syringe

When an injection has stopped, the Main Screen will be redisplayed. At that time the system will need to be re-loaded and re-armed to continue with another procedure. In the concluding step, the patient must be disconnected from the EmpowerCT Injector System before the syringe is unloaded.

2.7.1 Disconnect the Patient from the Injector System



Failure to carefully follow the instructions in this Section before proceeding to remove the syringe may result in serious injury to the patient.

1. Disconnect the CT Injector's coiled tubing from the patient. Close off the catheter or remove in accordance with site practice.
2. If an extravasation detection patch was used, carefully peel it off of the patient and discard it. Extravasation detection patches should never be reused.

2.7.2 Remove the Syringe

1. Tilt the Injector back into the upright position.

When **REPLACE SYRINGE** appears in the lower right corner of the Injector Controller's screen, press and hold down its membrane button until the word **STOP** is displayed instead. Release the button and wait for the syringe plunger to fully retract. When the injection ram is fully retracted, the menu option **AUTO-INITIALIZE** will appear on the Injector display.




CAUTION: Do not kink or occlude the coiled tubing while replacing the syringe. This will cause a vacuum to develop in the syringe, which in turn will result in the syringe plunger recoiling when the Injector ram reaches the REPLACE SYRINGE position. This could result in contrast spillage and syringe breakage.

2. Open the syringe door.
3. Remove and discard the syringe, along with the coiled tubing using institutional procedures for the disposal of bio-hazardous waste.

2.8 Clean Up and Storage

At the conclusion of a day's procedure load, or in the event of any accidental spill on the equipment, clean the EmpowerCT Injector System using the following procedures.

1. Power off the Injector System using the rocker switch located on the underside of the Injector Controller's screen.
2.  Dampen a paper towel with mild hospital-grade disinfectant cleaner, and carefully wipe off any dirt or spilled fluids. Do not use strong disinfectants or cleansers; do not allow any liquid cleaner to get inside the EmpowerCT Injector System. Never submerge either unit in water. **Failure to follow these instructions may damage the equipment or create the possibility of an electrical shock to the technologist or patient.**
3. Clean the Remote Control with a soft towel and mild detergent. Clean the screen with a soft towel and a computer monitor cleaning agent.

When not in use, the Remote Control and Injector System should be stored in a safe place, away from dust, extreme or quickly changing temperatures, or the possibility of spills or other accidental damage.

SECTION 3: ADVANCED PROGRAMMING FEATURES

The EmpowerCT Remote Control has a wide variety of injection programming features, a few of which were described briefly in the preceding section. Most of these features are accessible from the program screen.

To get to the program screen, begin at the Main Screen of the Remote Control as shown in Figure 3.1.

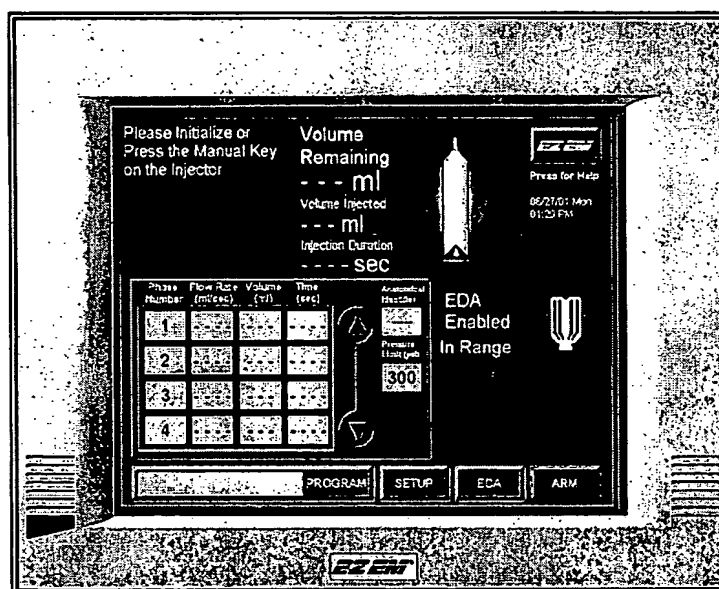


Figure 3.1 Main Screen

If this screen is not displayed, but the Remote Control is on, press the **RETURN** button at the lower right corner of the screen until the Main Screen is displayed.

On the Main Screen, press the **PROGRAM** button near the middle of the bottom of the screen. After this button is pressed, the program screen will be displayed as shown in Figure 3.2.

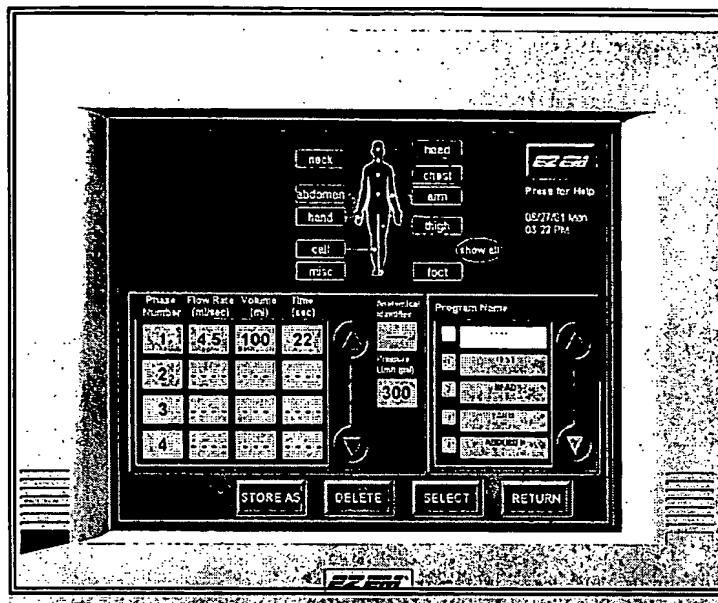


Figure 3.2 Program Screen

Among other things, this screen allows examining and selecting existing programs, creating and storing programs, and deleting old programs that are no longer needed. All of these features are described in the following sections.

3.1 Reading and Creating Programs

The basics of reading and creating programs are described in the preceding section, beginning in Section 2.5. Everything related to these activities works the same in the program screen as it does in the Main Screen. To review briefly: A program is a series of phases containing flow rates and volumes. These phases are listed sequentially in a phase table in the lower left quadrant of the screen.

If the program is more than four phases long, all of the phases cannot be listed on the screen simultaneously. If there are phases that are currently not visible, the up or down arrow to the right of the list will be green.

If an arrow is green, press on it to scroll the list of phases up or down. The list will scroll one phase for each press and release of the appropriate arrow, or will scroll continually if an arrow is held down.

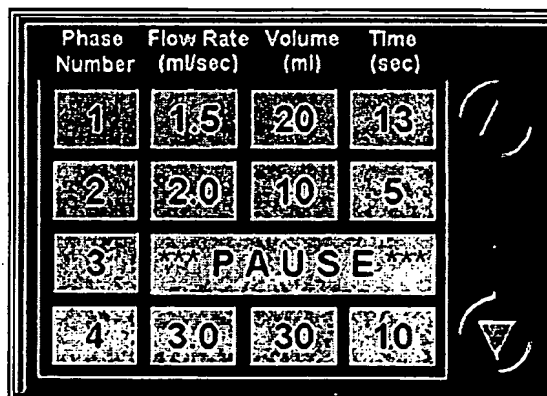


Figure 3.3 Highlighted (Green) Scroll Arrow

Pressing on a flow rate or volume can alter the information in the phase table. The duration will be updated automatically.

Following a press on a flow rate or volume, a corresponding pop-up Range window will be displayed. Using the buttons in either of these windows, enter the desired value and then press **ENTER** to add it to the phase table. If a mistake is made, press **BKSP** to erase it one character at a time, **CLEAR** to erase the value completely, or **CANCEL** to leave the Range window without specifying a new value.

To enter a ***** PAUSE ***** (which will suspend the program's execution until it is told to resume) or to delete an unwanted phase, press directly on the phase number. In the resulting window press **PAUSE** or **DELETE**, as appropriate, then press **ENTER**; to exit from that window without entering a pause or delete, press **CANCEL**.

3.1.1 Pressure Limit and Delay To Scan

In addition to the above features, in the program screen or the Main Screen, a pressure limit or a delay to scan can be specified for an entire program. These values are entered just to the right of the phase table.

The **Pressure Limit** parameter specifies the maximum allowable syringe pressure for a programmed injection procedure. If the pressure of the contrast media being injected reaches this value, the Injector System will slow down to maintain this pressure value. If the Injector System has to run at less than 75% of the flow rate originally requested, the phase information on the Remote Control will begin to blink. If the injection rate falls to 0.1 mL/sec for 5 seconds (essentially a stall), the injection will pause with an "overpressure" message. The user can then correct any problems with the patient, coiled tubing, or catheter before electing to resume the procedure.

Delay to Scan specifies, in seconds, how long the Remote Control should wait after an injection begins, before annunciating a "start the scanner" voice prompt or tone. If the screen does not include a place to enter a delay to scan, but one is desired, see the discussion about enabling scanner messages, beginning in Section 4.1.4.

To change either of these values, press directly on the value to be changed and a corresponding pop-up Range window will be displayed, just as with flow rates and volumes.

These windows work exactly like the Range windows for flow rate and volume. Specify the desired value, then press **ENTER**.

3.1.2 Anatomical Identifiers

The above listed features are all available when creating or viewing a program in the Main Screen. Also displayed in the Main Screen is the **Anatomical Identifier** for the current program. The anatomical identifier permits the user to associate an injection protocol to a specific part of the human anatomy. It serves as a way to group all programmed protocols to a specific body part. This identifier specifies the primary part of the body that is expected to be scanned when running its associated injection protocol.

SECTION 3: ADVANCED PROGRAMMING FEATURES

For example, if the user has multiple injection protocols for scanning the abdomen, by associating the abdomen anatomical identifier to them as part of the stored program, they can be retrieved by anatomical location along with its specific naming convention.

To associate an anatomical identifier for the program currently displayed in the program screen, press on the anatomical identifier value adjacent to the program phases.

The value will be given a white background. Then, using the human body diagram at the top of the screen shown in Figure 3.4 press on the name of the part of the body associated with the program. The anatomical identifier value will change to the body part pressed.

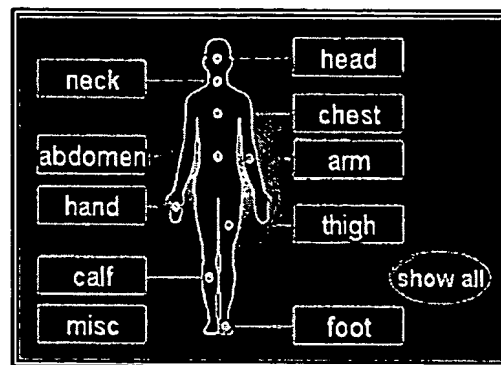


Figure 3.4 Anatomical Identifiers Diagram

3.2 Examining and Selecting Existing Programs

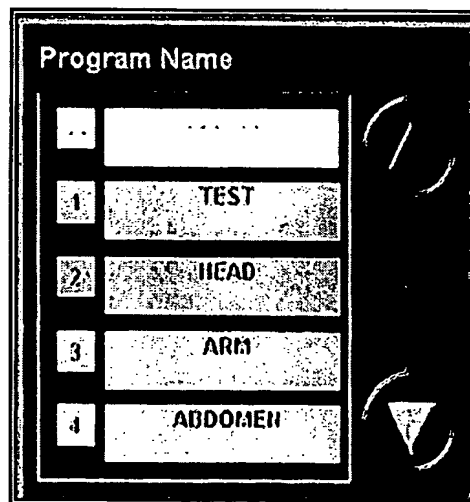


Figure 3.5 Program Name List

The lower right portion of the program screen displays a list of program names.

Scroll up and down through this list of 50 by pressing on the arrows located just to the right of it. These arrows will cause the list to scroll down by one program each time the appropriate arrow is pressed and released, or will scroll continually if an arrow is held down.

You can also sort the program list to only those programs intended for use when scanning a particular part of the body, by pressing on any anatomical identifier contained on the human body diagram at the top of the screen. To return to the full list of programs after viewing an anatomically limited list, press on a program name then on **Show All**.

To examine the contents of a stored program, press on its name. The program will be displayed in the phase table, with the corresponding anatomical identifier, pressure limit, and delay to scan.

SECTION 3: ADVANCED PROGRAMMING FEATURES

To select the current program as the one to use in the Main Screen, press **SELECT** at the bottom of the screen. The Main Screen will be displayed with the chosen program listed at the lower left.

To return to the Main Screen without selecting a program, press **RETURN** in the lower right corner of the screen.

3.3 Modifying Existing Programs

To change the name of a program after it is displayed, press on its name again. An alphanumeric pop-up window will be displayed as shown in Figure 3.6.

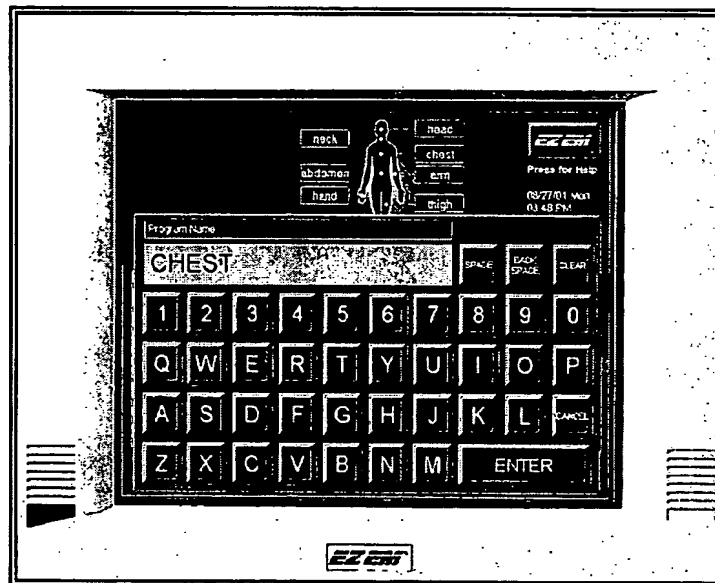


Figure 3.6 Program Name Window

This window works like all the Range and other numeric-only windows seen elsewhere, except that this window also allows entry of letters and spaces; the backspace is spelled out instead of being abbreviated **BKSP**; and the **ENTER** button will not appear until a name at least one character long has been specified. To save a new program name, press **ENTER**.

To make any other adjustment to a program – i.e., change its phase information, anatomical identifier, pressure limit, or delay to scan – use the same techniques as would have been used to set that criterion originally.

3.4 Saving and Deleting Programs

To store changes to an existing program back under the same program name, press **SAVE** near the lower left of the screen. You will be asked to confirm that you want to permanently overwrite the previous information for that program.

To save changes to an existing program as a new program, or to save a new program that has just been created, press **SAVE AS**. The program will be saved in the next available slot in the program name list, up to a maximum of 50 programs. If an attempt is made to use **SAVE AS** to save a program that is identical to an existing program, a message will state which other program is the same as the current one, and ask if you wish to proceed anyway.

Once a program has been saved, it will be stored in the Remote Control's memory, until someone changes it or deletes it. To delete a program, press its name in the program name list, then press **DELETE** at the bottom of the screen.

SECTION 4: ADMINISTRATIVE FEATURES

4.1 The Setup Screen

The setup screen is displayed following a press on the **SETUP** button at the bottom of the Main Screen as shown in Figure 4.1.

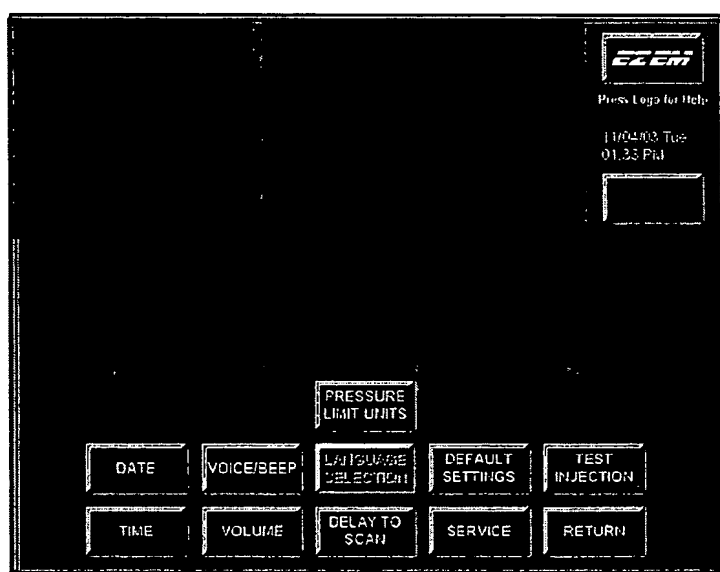


Figure 4.1 Setup

The options available from the setup screen are each accessible via the corresponding button:

SHUTDOWN – Shuts down the Remote Control’s software.

DATE – Changes the date on the Remote Control.

TIME – Changes the time and/or time zone on the Remote Control.

VOICE/BEEP – Activates or deactivates voice messages, except for “Check for Possible Extravasation” which cannot be deactivated.

VOLUME – Changes the volume of the voice messages or the bell that sounds when the system pauses.

DELAY TO SCAN – Enables or disables the ability to program a time-delayed “start the scanner” voice message.

DEFAULT SETTINGS – Restores all the settings in the setup screen to their factory default values.

SERVICE – Proceeds to a service menu. This option is only for use by E-Z-EM authorized representatives and is password protected.

TEST INJECTION – Sets the parameters for conducting a test injection immediately before each main injection.

LANGUAGE SELECTION - This option is only for use by E-Z-EM authorized representatives and is password protected.

PRESSURE LIMIT UNITS – Change the units displayed for the Pressure Limit from psi to KPa to bars.

RETURN – Returns to the Main Screen.

4.1.1 Changing the Date

When **DATE** is pressed in the setup screen, the Date window is displayed. This window operates like all the other numeric entry windows, except for the **Date Display Format** button, which toggles the date display between the two most commonly used formats, DD/MM/YY and MM/DD/YY.

To specify a new date for the Remote Control to use, enter exactly the six desired digits (e.g., 030302 for March 3rd, 2002), and press **ENTER**.

4.1.2 Changing the Time

When **TIME** is pressed in the setup screen, the Time window is displayed. This window operates like all the other numeric entry windows, except for the three special buttons in the rightmost column:

- To toggle between using regular time and military time, press the **Time Display Format** button.
- To change the time zone, press **Time Zone**, press the desired time zone, and press **OK**.
- To set the time, enter a four-digit time (e.g., 0315 for 3:15), then press **AM/PM** if necessary to switch between those.

Note that the Remote Control does recognize, use, and automatically adjust for the changes between daylight savings time and standard time, though in this window it will always refer only to using standard time.

Press **ENTER** to save the specified time settings.

4.1.3 Changing the Audio Volume

When **VOLUME** is pressed in the setup screen, a window is displayed that contains two volume bars.

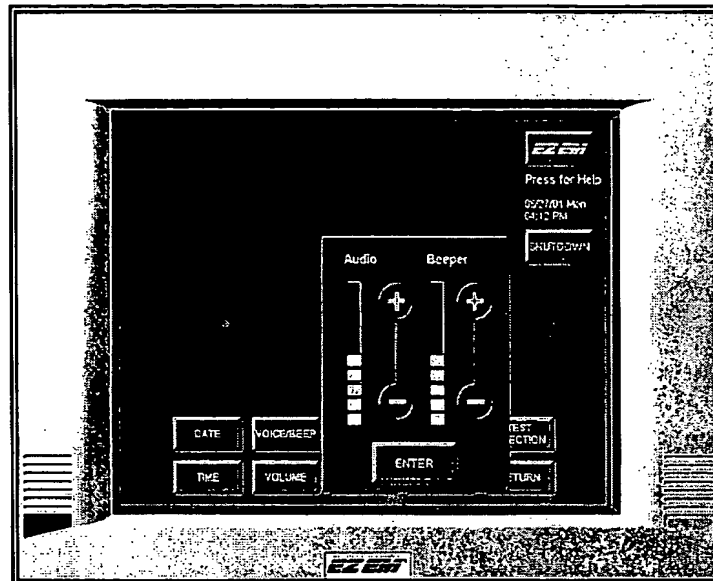


Figure 4.2 Volume Bars

The bar on the left represents the volume of the voice messages. The bar on the right represents the volume of the tone that sounds when an injection is paused. No changes are possible to the volume of the beeps the Remote Control makes when the touchscreen is pressed.

To adjust either of the displayed volume bars, and the corresponding volume, press the plus or minus button immediately to the right of the bar to be adjusted. The Remote Control will play an example of the new volume to allow confirmation that it is what is desired.

When satisfied with the volume settings, press **ENTER**.

4.1.4 Enabling or Disabling the "Start the Scanner" Voice Message

When the **DELAY TO SCAN** button is pressed in the setup screen, the **DELAY TO SCAN** window is displayed.

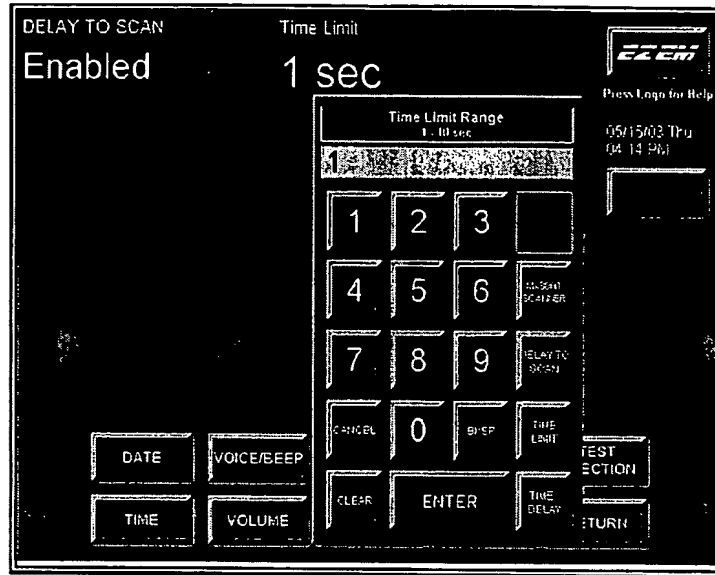


Figure 4.3 Delay to Scan Window

Most of the functionality in this window is only useful to an E-Z-EM authorized representative. However, to disable or enable the ability to set a Delay To Scan value when programming the Remote Control, press the **DELAY TO SCAN** button until the desired state is shown in the upper left corner of the screen. Then press **ENTER**.

To leave this window without making any changes, press **CANCEL**.

4.2 Performing Test Injections

After the EmpowerCT Injector System is first **armed** but before pressing **RUN**, the lower left corner of the Injector screen displays the **TEST INJECTION** option.

If this option is selected by pressing the associated membrane panel button, the EmpowerCT Injector System will perform a pre-determined test injection. If this test injection is paused or allowed to conclude, the EmpowerCT Injector System remains in **arm** mode.

The volume and flow rate for the test injection is initially set up in the Setup menu. The volume range is: 1-10 mL and flow rate range is: 0.1-10 mL/sec. Defaults are 2.5 mL/sec for 10 mL. To change these values, press the **TEST INJECTION** button in the setup screen.

4.2.1 Adjusting the Test Injection Settings

When the **TEST INJECTION** button is pressed in the setup screen, a Flow Rate Range pop-up window is displayed. This window is identical to the Flow Rate Range window used to enter flow rates for individual program phases, except for the two buttons at the lower right. The **TEST FLOW RATE** button does not do anything, but the **TEST VOLUME** button goes to a Volume pop-up window.

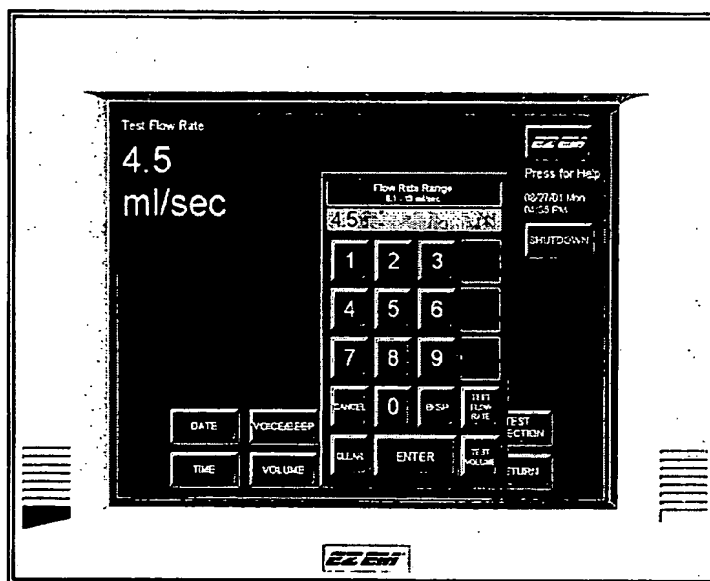


Figure 4.4 Test Injection Flow Rate Range Window

Similarly, the Volume Range window is identical to the Volume Range window used to enter volumes for individual program phases, except for the two buttons at the lower right. The **TEST VOLUME** button does not do anything, but the **TEST FLOW RATE** button goes to the Flow Rate Range window. Using either or both of these windows, set the desired flow rate and volume for all test injections, then press **ENTER**. To exit without making any changes, press **CANCEL**.

4.3 Shutting Down the System

4.3.1 Powering Off the Remote Control

To power off the Remote Control, press **RETURN** at the lower right of the Remote Control's screen, until the Main Screen is displayed. Then press **SETUP**.

In the setup screen, press **SHUTDOWN**. When asked whether you wish to proceed, press **YES**.

Wait for a message to say it is now safe to power off your computer, then power off the Remote Control using the rocker switch on the right underside of it.

It is highly recommended that this shutdown procedure always be followed when powering off the Remote Control. The Remote Control system contains a hard drive. This shutdown procedure will ensure that all open files on the system are properly closed and maintained.

4.3.2 Powering Off the Injector System

To shut down the Injector System, follow the normal process of concluding an injection and unloading the syringe, then power off the Injector System using the rocker switch behind the right side of the Injector Controller's screen.

4.4 Help Feature

The Empower CT Remote Control has a feature to aid the user in the use of the Empower CT Injector System. This feature is called the Help feature. It is activated by pressing on the E-Z-EM logo on the Main Screen as shown in Figure 4.5. The Help feature can also be activated on the Program and Setup screens.

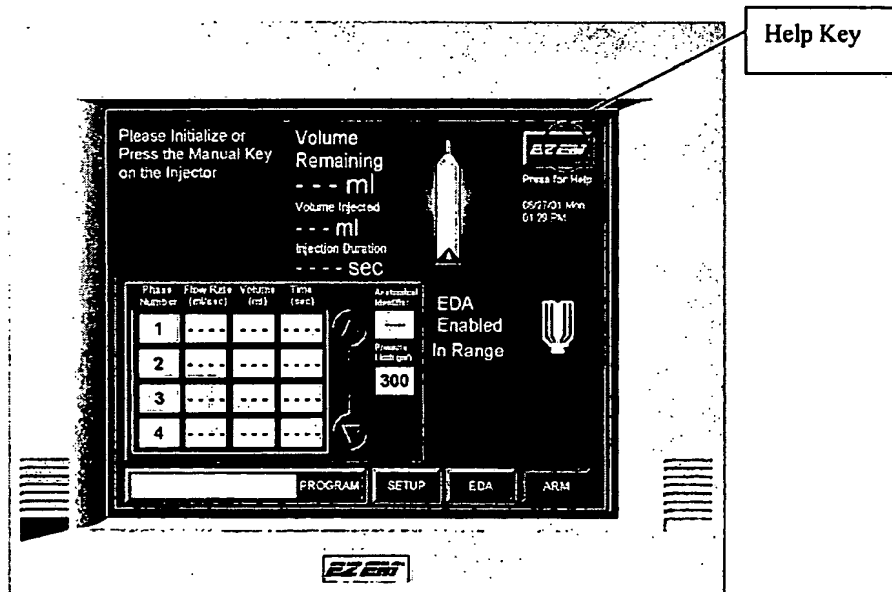


Figure 4.5 Main Screen

Once the key is pressed, the Main Help screen will be displayed as shown in Figure 4.6 below.

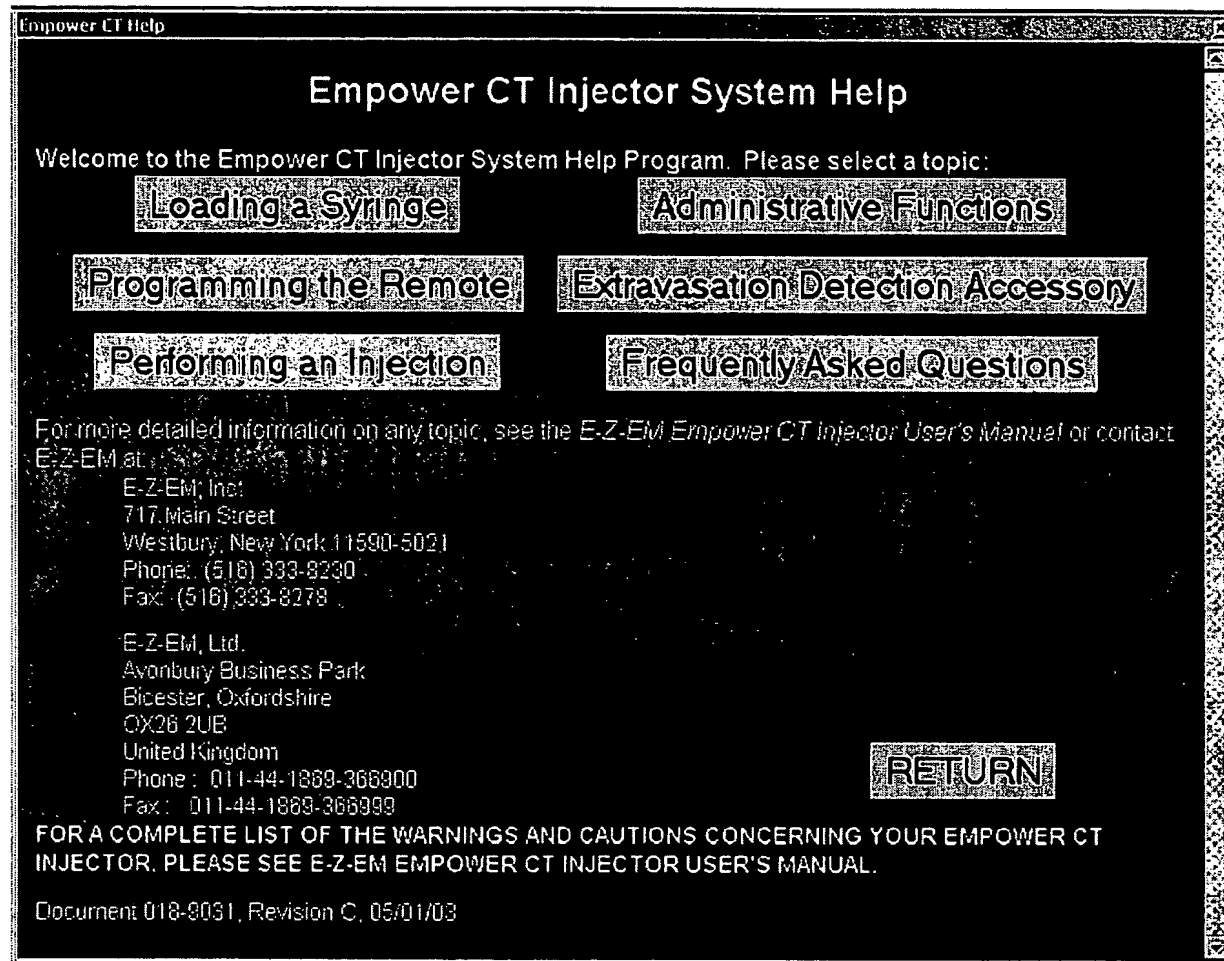


Figure 4.6: Main Help screen

Each key topic will display a set of instructions. In each topic, the **RETURN** key is used to return to the previous Main Help screen. To exit the Help system, press the **RETURN** key on the Main Help screen.

SECTION 5: UNDERSTANDING EXTRAVASATION DETECTION

5.1 Suggested Techniques for Minimizing Extravasations

Clinical personnel monitoring the patient can detect extravasation of contrast media. It is recommended that CT Injector users follow best clinical practices and standards of care established by their respective institution when monitoring the patient for extravasation during contrast injection.



To minimize the possibility of an extravasation we suggest the following:

- Use a catheter that is 20 gauge or greater in the largest vein possible. E-Z-EM recommends an Angiocath®, Angio-Set® or equivalent. (Angiocath® and Angio-Set® are registered trademarks of Becton Dickinson and Company.)
- Minimize the effects of patient movement by taping the catheter firmly to the patient's skin. Use of an Angiocath-type butterfly permits easy insertion and secure taping.
- The forearm is the preferred location for venipuncture. This position permits the arms to be placed over the head during body scans without the danger of kinking either the catheter or tubing. Use of a 60-inch/1.5-meter, coiled, low-pressure tube also reduces the motion effects associated with table movement.
- Do not use catheters that are kinked or that have been kinked.
- If a patient presents with one or more indwelling intravenous lines, do not assume that the intravenous set is acceptable for use with the EmpowerCT Injector System. If possible, place a new intravenous line.
- Central venous lines and heparin-locks are not recommended.
- To augment clinical monitoring during contrast media injection and to help detect potentially serious extravasations, E-Z-EM recommends use of the Extravasation Detection Accessory (EDA) in conjunction with the EmpowerCT Injector System. If you have purchased the EDA please refer to section 5.2 for the proper use.

If your Injector System does not include an EDA and you would like to obtain one, please contact your E-Z-EM representative.

5.2 EmpowerCT Injector System with the Extravasation Detection Accessory



It is important for the owner/operator of the “Extravasation Detection Accessory” (EDA) to understand that this device is to be used only by trained, qualified and authorized personnel. Additionally, individuals using this device must be alert and attentive to the operation of the system while it is connected to the patient. The EDA is provided as an auxiliary device feature, which assists users in the detection of a possible extravasation. As with all equipment that monitors a patient’s physiological response, it is not intended as a substitute for observation and intervention by a trained healthcare professional. Diligence on the part of the owner/operator is an essential requirement of overall patient safety.

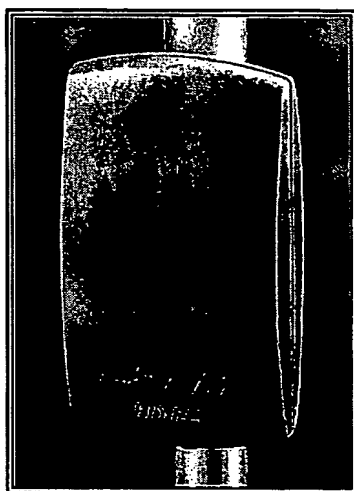


Figure 5.1 EDA Module

Throughout this manual, reference is made to E-Z-EM’s EmpowerCT Extravasation Detection Accessory or “EDA.” The EDA is a device mounted on either the floor stand or ceiling suspension system as shown in Figure 5.1. Its function is monitoring for, and assisting in detecting contrast media extravasation during an injection.

The detection capability of the EDA is seamlessly integrated with the functionality of the Injector System. If an extravasation is detected the EDA will pause the EmpowerCT Injector System automatically. If use of this accessory is not desired for a procedure, the EDA can be disabled for any injection protocol.

The EDA uses the principle of bio-impedance to locally monitor the patient’s tissue over the outlet of the venous access catheter. If for some reason, contrast should start to extravasate local to the outlet of the catheter, the tissue bio-impedance underneath the EDA patch changes. The EDA system monitors this change over a period of time. Based on the injection flow rate, it establishes a permissible bio-impedance change indicative of 20 mL maximum contrast media extravasation. Once this threshold is reached, the EDA communicates this information to the Injector System. At that time the contrast injection is paused and the user is informed of the occurrence of a possible extravasation.

The sensitivity and hence effectiveness of the EDA patch is greatest for contrast extravasations that accumulate in the tissue directly underneath the patch. Extravasations of this type most commonly exhibit a local wheal underneath the patch.

In cases where extravasated contrast migrates into sub-cutaneous tissue or septal planes, the sensitivity and effectiveness of the EDA patch is lower than those where it directly accumulates underneath the patch. These types of extravasations typically do not reveal any localized whealing or swelling. Additionally, for extravasations that initiate downstream or distal to the end of the catheter beyond the area of coverage of the EDA patch, the EDA is not designed to detect bio-impedance changes associated with this extravasation condition.

Based on this, the EDA augments and enhances a user's best clinical practice in their ability to provide the highest standard of care. As designed, the EDA continues to monitor the patient during the latter part of the contrast injection just prior to or during the scanning sequence when the patient is typically left alone in the scanner room when the x-ray equipment is in use. To realize maximum effectiveness with the EDA, it must be done so in conjunction with close monitoring by a trained clinician.

For systems configured with the EDA, this accessory device is designed to augment clinical monitoring for contrast media extravasation. The EDA is not designed to be a full or partial substitute for the normal diligence associated with best clinical practices when monitoring for extravasation.

5.2.1 Proper Loading and Placement of the Extravasation Detection Patch

Note: Use only E-Z-EM's EDA Patch (cat#: 7881)

The ability of the EDA to successfully detect an extravasation is dependent on proper placement of the Extravasation Detection Patch. It is important for all users of the EmpowerCT Injector System with EDA to read and understand the contents of this section.

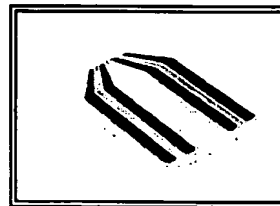


Figure 5.2 EDA Patch

1. Loading and placing the patch should only be performed after completing the steps required in Sections 2.1 through 2.5 of this manual. Which includes powering up the equipment, loading and filling the syringe with contrast media, properly preparing the patient, connecting the coiled tubing to the syringe and catheter and programming the remote control.

Note: Prior to loading and placing the EDA patch, the EmpowerCT Injector System must be in the stop mode.

Note: After being powered-up, the Injector Controller and Remote will display the **EDA ENABLED OUT OF RANGE** message until the Extravasation Clip is properly connected to the system and the Extravasation Detection Patch is properly placed on the patient.

2. Route the patient end of the Extravasation Clip parallel to the coiled extension set and bring the connector end of the cable that holds the Extravasation Detection Patch near the patient's catheter site.
3. Hold the connector between your index finger and thumb. The underside of the connector should be supported by your index finger. To open the connector, locate the top button and push back with your thumb (see Figure 5.3).
4. Observing aseptic technique, open the foil pouch containing the Extravasation Detection Patch and remove the patch.
5. Bend down the backing tab at the connection end of the patch. Do not remove the patch from the backing at this time.

SECTION 5: UNDERSTANDING EXTRAVASATION DETECTION

6. Insert the connection end of the patch into the connector as shown in Figure 5.3.

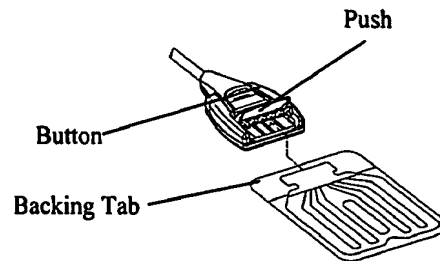


Figure 5.3 Connector's Latching Mechanism

7. Using your thumb, press on the clamp, shown in Figure 5.4, until latched.

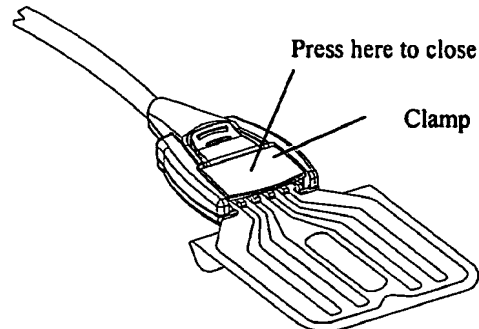


Figure 5.4 Securing the EDA Patch

8. When you are ready to apply the patch to the patient, peel off the protective backing on the patch by pulling on the tab to expose the adhesive.

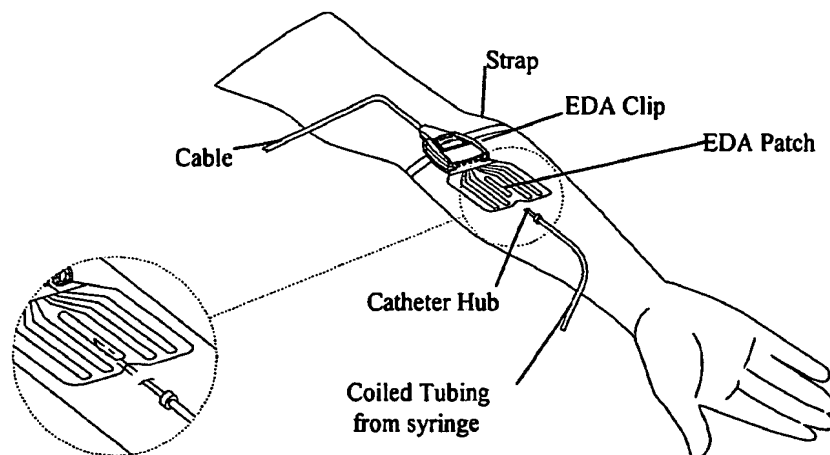


Figure 5.5 Applying Extravasation Detection Patch to Patient

9. Carefully place the patch on the patient's skin adjacent to the catheter Luer connection. Position the patch such that its center is located over the distal end of the catheter. **Do not cover the catheter entry point with the patch.** The EDA patch's notch should surround the catheter, but not impede it in any way. There must not be any tape under the patch, or it may not work correctly (Figure 5.5 and Figure 5.6)

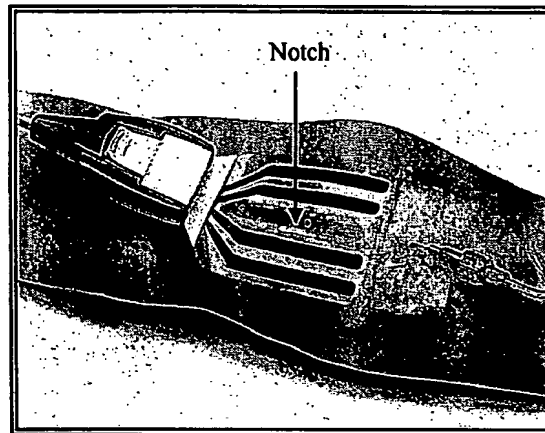


Figure 5.6 Arm with proper placement of EDA patch

10. Gently press the patch over the patient's skin. Observe the following:
 - Make sure that the entire surface of the patch is in contact with the patient's skin.
 - Press down wherever necessary to eliminate all air gaps.
 - Do not place the patch over adhesive tape, bandages, or other topical dressings.
 - Patients with excessive amount of body hair may need to be locally shaved prior to placement of catheter and patch.
11. Using the arm strap, secure the Extravasation Clip to the patient directly adjacent to the connector.
12. Carefully check the catheter and Extravasation Detection Patch placement prior to operating the EmpowerCT Injector System.
13. Upon placing the patch on the patient, the Injector Controller and Remote will briefly display **EDA ENABLED NO BASELINE** followed by **EDA ENABLED IN RANGE** message. This indicates that the Extravasation Clip is properly connected to the Injector system, and the Extravasation Detection Patch has been properly placed on the patient. The injection is ready to begin. Refer to section 2.6 "Perform the Injection".
14. If the **EDA ENABLED NO BASELINE** or **EDA ENABLED OUT OF RANGE** message should be displayed at any time after the EDA connections have been completed, it is an indication that either the Extravasation Clip is not properly connected, or the Extravasation Patch has not been properly placed on the patient. Check the Extravasation Clip to ensure that it is properly connected and /or the EDA patch has been correctly placed on the patient.

15. To remove the Extravasation Detection Patch, gently peel it off the patient's skin. Then push back on the connector's top button and remove the patch from the connector. Dispose of the patch. **Do not reuse the extravasation detection patch.**

The Injector Controller and Remote will display the **EDA ENABLED OUT OF RANGE** message upon removal of the patch from the patient.

5.2.2 Detecting an Extravasation during an Injection

If a possible extravasation is detected during the **run** mode, the following will occur:

- The system will halt the injection sequence.
- The system will go into the pause mode.
- The Injector Controller will display **CHECK FOR EXTRAVASATION**.
- The Remote Control will activate a verbal message **CHECK FOR POSSIBLE EXTRAVASATION** three times.
- The Remote Control will display **CHECK FOR POSSIBLE EXTRAVASATION** and will display **Press RUN to Continue or Press EDA button to Disable** in the top left corner of the screen.

After checking the patient for possible extravasation and an extravasation is found, a qualified healthcare professional must determine the appropriate corrective action to be taken.

If it is determined that the procedure must be stopped, press the **STOP** button on the Remote Control.

The injection procedure can be continued by pressing the **RUN** button on the Remote Control, or pressing the pendant switch.

The injection procedure can also be continued with EDA disabled using the following procedure:

1. While in the **pause** mode, press the **EDA** button on the Remote Control. The Injector Controller and Remote Control will display **EDA USER DISABLED** in the EDA Message Area.
2. Press the **RUN** button on the Remote Control, or press the pendant switch.

During the injection procedure, you can manually pause the system by pressing the pendant switch, touching the Remote Control screen or pressing one of the three middle buttons on the Injector Controller.

5.2.3 Completing the Injection

After the injection procedure is complete, disconnect the EDA Clip from the EDA patch. Remove the Extravasation Detection Patch from the patient's arm and dispose of it in an appropriate receptacle. **Do not reuse the extravasation detection patch.**

Place the EDA Clip back into its holder.

SECTION 6: SERVICE AND WARRANTY

If you have any questions or concerns regarding your EmpowerCT Injector System, Remote Control, or E-Z-EM supplies, contact E-Z-EM Customer Service at 516-333-8230.

In addition, on the Remote Control, press on the E-Z-EM logo at the upper right corner of the screen to access the Remote Control built-in Help system.

A warranty card is enclosed with the literature pack, which is sent under separate cover. It is important that this card be filled out and dated at the time of installation. This card has been postage paid for your convenience. If this card was not mailed or was lost, please contact E-Z-EM immediately for a replacement.

The EmpowerCT Injector System and its accessories are warranted against defects in material and workmanship for 12 months from the date of installation. Please refer to your warranty card for further details. E-Z-EM offers a variety of service contracts to cover your new EmpowerCT Injector System when the original warranty expires. For information about the warranty or a service contract, please contact your E-Z-EM representative.

Note: Unauthorized modifications or service to the EmpowerCT Injector System will void your warranty.

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